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Innovation in Public Health: a behavioral and design sciences approach

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Innovation in Public Health: a behavioral and design sciences approach

By

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Abstract

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The widespread prevalence of chronic diseases has become a healthcare crisis worldwide. The incidence of chronic diseases has dramatically increased despite large expenditures in their prevention. More effective and efficient public health solutions are needed. To take advantage of novel findings in genomics, metabolism and physiology, innovative translational and implementation methods are needed. Operationally, *innovation is understood as to develop a solution that achieves equal or greater effectiveness with less resource(s) than the previous ones.*

How can we reduce the level of uncertainty when aiming for innovation in public health?

The main assertion of this dissertation is that, holding constant resources and time, we are more likely to develop an innovative solution with an iterative problem solving process of multiple cycles of feedback than with a more systematic solving process with only one cycle. This dissertation proposes the use of design sciences methods and principles to guide trial-error iterations during the innovation process.

Design sciences encompass a wide variety of disciplines that are engaged in the creation and manufacturing of novel products, objects and solutions such as in architecture, engineering, computer science, and artificial intelligence. Design theorists have distilled a set of principles to practice "evidence-based" design, by analyzing how different design disciplines tackle problems. Three of the most important principles are to break down complex problems into smaller, functional modules, to prioritize functionality of a solution over theoretical or technical preferences and to build solutions iteratively and by progressive approximation.

Design theorists have also concluded that some problems cannot be fully understood before solution generation begins. This can be contrasted with the traditional, but weaker, approach of investigators who define problems using only findings of past

studies and pre-design interventions to address those problems before an intervention project begins—for example in a grant application. This approach keeps the problem definition and the intervention design fixed even as more information becomes available that challenges the original problem statement and intervention design. Design science theory and methods explain the drawbacks of this approach and the value of using more iterative, forward-oriented design methods.

The prospect of successfully supporting people to improve their health through dietary and fasting strategies motivated the development of the Dietary Intervention Canvas framework described in this dissertation. This framework is intended to guide the design and development of innovative and more effective dietary interventions. It integrates principles from design, behavioral and nutritional sciences with a novel approach to conceptualize dietary interventions. It is located at the intersection of translating experimental findings into clinical and population level interventions. This framework was built by carefully analyzing dietary behaviors across different cultural settings and life course stages. It was also based on an analysis of the behavioral strategies utilized by people who succeeded in long-term dietary change and weight loss.

The Dietary Intervention Canvas was used to tackle a problem that currently has high levels of uncertainty: remission of type 2 diabetes. Novel physiological findings reveal that remission of type 2 diabetes mellitus may be achievable. However, such experimental findings needed to be translated into interventions that consider patient characteristics and the cultural milieu of the target population.

In this dissertation, the Dietary Intervention Canvas was applied to distill key elements of the vast literature regarding diabetes causality, identify potential mechanisms of remission, translate them into medical nutrition therapy specifications, and formulate dietary intervention concepts with promising cultural acceptability and feasibility. The intervention was focused on patients in semi-rural settings in Mexico. Literature review, interviews with key stakeholders including members of the target population, healthcare providers and primary caregivers led to the development of multiple intervention concepts and prototypes. The result was a set of specifications to build intervention components that support patients to make dietary, psychological and physiological changes to achieve remission of the disease.

The dissertation is organized as follows. The first paper provides a summary of the analysis that describes the behavioral foundations of this dissertation. It addresses the seemly paradoxical observation that people interested in improving their health through dietary changes fail to sustain those changes. The second paper describes in detail the Dietary Intervention Canvas framework. The third paper describes its application to develop an intervention prototype for remission of type 2 diabetes within the Mexican context.

This dissertation describes a new path forward in the critical effort to develop more successful interventions by drawing on design science theory and methods as well as knowledge from multiple disciplines. The Dietary Intervention Canvas is a novel and

promising framework intended to help researchers and practitioners support people to achieve seemingly unreachable goals—such as the remission of type 2 diabetes. Further research is needed to apply the Canvas in diverse populations and evaluate the outcomes.

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Dedication

To all the souls that shared this journey. Mom, dad, brothers, partner, children, friends. May god bless you.

In the name of those who, like subject D, relentlessly sought a solution for those health problems long considered insolvable.

And finally, this dissertation is for you - Mexican and American people.
It was your generous support that made this possible.

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Curriculum Vitae

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Chapter 1. Introduction

Public Health is facing many challenges where innovation is needed. Problems such as the prevention of diabetes or the prevalence of AIDS require innovation. But, what is innovation? Though debatable, an operational definition adopted during the work of this dissertation is: to develop an intervention that achieves equal or greater effectiveness with less resource(s) than the previous ones.

However, innovation implies uncertainty. A degree of uncertainty that is not usually welcomed in medical and health sciences. These disciplines adopt a risk-minimizing strategy, eliminating as much as possible uncertainty. This implies that innovation will not be sought, at least not actively. Strategies such as evidence-based medicine are preferred. But what do we do when the available evidence does not offer a good-enough solution to reduce disease and mortality burden?

An area where innovation is urgently needed is dietary change in the population. At least 10% of the global disease burden is directly attributable to dietary factors (Lim, 2010). Worldwide and for more than 30 years, improving the diet of the population has been an important target of health promotion. Unfortunately, more often than not, dietary interventions and policies fail short of fulfilling their potential. Most countries do not achieve most of their dietary goals. As a consequence, diet-related diseases have grown rampant in the past 25 years. The fight against obesity, cardiovascular disease, stroke, diabetes, fatty liver disease, arthritis and several other diseases is in sore need of new strategies.

The question is: how do we promote dietary change in an efficient and sustained way, especially in those suffering of diet-related morbidities? With health, behavioral and design sciences as my theoretical framework, I pondered over this question during my doctoral studies. Eventually, I concluded that two key aspects needed to be addressed.

The first aspect, as described in Chapter 2 of the dissertation, is to identify what kinds of behavior change techniques are most useful to promote dietary change. In the first paper, using a set of 59 interviews with successful cases of dietary change and weight loss, I explored their behavioral strategies for dietary change. These cases are worth studying because they were more successful than participants in landmark studies of weight loss.

The second aspect, as described in Chapter 3 of the dissertation, is to improve public health design methods. These methods are a mix of health, biomedical and social sciences methods. But design sciences methods are largely absent from them. How could we use design sciences principles and methods to develop dietary interventions? After a very long iteration process, I formulated a new method, the “Dietary Intervention Canvas”, presented in the second paper. It is meant to be used along with mainstream public health design methods.

After addressing these two key aspects, the question was: does the new method help to develop innovative interventions? The third paper in Chapter 4 presents the use of the

Dietary Intervention Canvas (DIC) to address a public health challenge that requires innovation: diabetes care interventions. Initially set to improve management of the disease, the goal eventually switched, now aiming to achieve remission of the disease. As of today, remission of type 2 diabetes is still an area of great uncertainty, even at an experimental level. By applying the proposed method, we sought to develop an intervention proposal feasible in a specific context: the Mexican Ministry of Health.

The theoretical framework of this dissertation is heavily based on design sciences. Briefly, design sciences deals with the study of disciplines that develop new products, services and objects. It deals with that area typically associated with "artificial" things. As such, it is very familiar with the framing of practical problems and the development of solutions for such problems. Therefore, design sciences theory should be very useful to improve public health methods, especially those utilized in the synthetic phase, when new interventions, programs and policies are developed.

The papers can be described with a design sciences perspective. The first paper is a study of positive outliers, similar to extreme users of a product or service. Extreme users of a product or service tend to tweak or modify the initial product –our theories regarding weight loss- in order to satisfy their particular needs. The second paper is a method´s proposal that draws heavily from a computer sciences approach to decompose problems. Its strategy is first to break down complex problems into functional modules. Then each module can be solved independently. The third paper represents an example of using such approach for a complex problem: diabetes remission. Instead of focusing on the problem space –the study of the causes of the disease- we focus on the solution space – how the disease has been sent into remission or cure-. Rather than aiming for a general cure of the disease, we focus on modular causes, for which it might exist a solution. In turn, this intervention concept is iterated until a culturally and operationally feasible intervention prototype is developed.

Finally, although I was convinced of the value of design sciences for public health, others were not. During the development of this dissertation, I kept asking for feedback from health scientists because they were meant to be the users of the method. I interviewed a few of them who were familiar with design thinking. They expressed their complete disdain for the solutions offered by design consulting firms. They claimed population health was not advertising and rigor on selection of causal mechanisms was completely missing from these consulting firms' work. Since I am a health scientist, I shared this insider view. It was not enough following a book on *new product development* or coming up with catchy intervention concepts. It was about rigor on physiological and behavioral sciences principles. It was a matter of redesigning our own health sciences methods with design sciences principles.

It is my wish that these critiques to previous attempts to integrate design sciences with public health methods are answered in this work.

After a long array of prototypes and iteration, this is the final manuscript of my dissertation, the log of my personal journey.

Chapter 2. Exploring the Solution Space for Weight Loss Maintenance: findings from Positive Outlier Cases

Abstract. In theory, large weight loss is sustainable. In practice, this is rarely seen. A promising approach to improve both theory and practice of weight loss interventions is to study "positive outliers", successful weight loss cases that occurred in the open population. In particular, it is important to study a key psychological factor, adherence to new dietary practices. The objective of this paper is to study the psychological strategies that these positive outliers use for long-term dietary change and to evaluate if these strategies vary between early and long-term maintainers.

Data and Methods. Positive outliers were identified from a convenience, open population sample of people who reported successfully maintaining weight loss. Inclusion criteria were to have lost more than 30 pounds and to have sustained that loss for more than 1 year. A total of 59 in-depth interviews were conducted with participants who met inclusion criteria. The initial set of categories to classify weight loss strategies was based on the 10 core processes of change of the Transtheoretical Model.

Results. At the time of interview, participants averaged a sustained weight loss of 55 lbs. for 3.5 years. They reported 19 different types of strategies: 10 from the core processes of change, 4 previously reported and five newly defined types. These new five types relate to concepts utilized in other disciplines. They were defined with concepts from economics, operations research and the biohacking community. These include *transactional cost*, *object use*, *lead time*, *bio-rhythm synchronization* and *forms of social support*. Compared to weight loss maintainers of less than two years, those with more than four years reported less often *consciousness raising* or *reinforcing techniques* and more often *transactional cost*, *lead time*, *object use* and *substance use*.

Conclusion. The spectrum of strategies reported by participants is more varied than predicted by the dominant health behavior theories. Between participants with early versus long-term weight loss maintenance, there are suggested differences in the frequency of reporting strategies of *object use*, *transactional cost* and *lead time* strategies. The identification of these new categories of dietary change strategies highlights the value of studying the experiences of positive outliers and the potential to expand interventions that promote successful, long-term weight loss.

Introduction

In theory, significant weight loss is sustainable (1). In practice, this is rarely seen. The causes of weight regain can be either physiological, psychological, or both. A meta-analysis of different weight loss interventions —dietary, physical activity, pharmacological and meal replacement treatment — estimated that the typical weight-loss trajectory has a plateau at around three to six months, followed by a weight regain pattern, averaging 40-70% at four years, regardless of the type of intervention (2). A key psychological factor seems to be the patient's lack of adherence to dietary regimens for weight loss maintenance. As a result, the US National Institutes of Health and other organizations have called for innovative ways to explore and develop interventions for weight loss maintenance (3,4).

Innovation is also required at a theoretical level. Behavioral theories often used to develop weight loss interventions were not developed to target diet, physical activity or weight loss, but rather focused on vaccination, protection from environmental threats, smoking cessation, etc. (5). Even well-funded theory-based interventions report a similar disappointing weight regain pattern in more than 50% of participants after four years (6). Therefore, a greater research focus is needed on how to evolve such theoretical approaches.

Scientific theories often advance by looking at the limits of understanding, the unexplained extremes (7,8). A potentially promising approach to improve both theory and practice of weight loss interventions is to study "positive outliers" (POs)—cases of major weight loss occurring in the open population. A similar approach has been used in the past to improve smoking cessation theory (9) and innovations in social development programs (10). There are already a number of studies of POs for weight loss maintenance (11–15). One of the most important is the National Weight Control Registry (NWCR), which studies a purposive sample of people who were able to sustain at least 30 pounds of weight loss for more than 12 months. Some of its findings were that weight loss maintenance is associated with a low-calorie diet and more physical activity regardless of the method used to achieve it (16); with longer self-monitoring of weight-related behaviors (17,18); and that it takes less effort over time to adhere to dietary and physical activity recommendations (19). While these and other findings have been useful, the NWCR is limited in the sense that it tested pre-specified hypotheses without in-depth instruments. PO studies use in-depth case analysis methods to generate new hypotheses that can be subsequently tested in intervention research.

The goal of this paper is to explore PO psychological strategies to sustain long-term dietary changes and weight loss. Objectives of this paper are to:

:

- Identify theoretical and empirical weaknesses of dietary changes and weight loss;
- Describe the value of studies of positive outliers;
- Identify the types of psychological strategies that POs use to sustain dietary change under a reduced weight condition;

- Compare strategies between early and long-term (four years) weight loss maintenance outliers; and
- Recommend improvements to psychological theories and interventions related to sustained weight loss.

Methods

Initial set of categories

The current analysis was performed with a "theory-neutral" view, so that any new insights could be tested later within different theoretical frameworks. First, a theoretical review was performed to identify a group of psychological change strategies that represented a mutually exclusive, collectively exhaustive set of categories. This criterion was set to enable a probabilistic approach in future studies[1]. The following theories were reviewed: the Health Belief Model, the Theory or Reasoned Action and Planned Behavior, the Transtheoretical Model of Change, the Social Cognitive Theory, the Precaution Adoption Model, Social Networks and Support Frameworks, the Theory of Self-Regulation, the Theory of Habit Formation, the Framework for Participatory Action Research, behavioral economics, the Health-Action Process Approach and the Fogg's Behavioral Change Model (5,20–31). Additionally, we reviewed taxonomies of behavior change (32,33).

No set of categories satisfied the initial criterion. The closest set to fulfill such criterion was the 10 categories of "Processes of Change" (PoC) drawn from Prochaska and colleagues' Transtheoretical Model of Change (TTM). It was originally defined in 1982 through the analysis of dozens of psychotherapy systems and through the study of positive outliers related to smoking cessation (34,35). It was later refined by studying other types of psychological change (36). The original 10 PoC included five major processes of change, each one with an experiential and a behavioral component: consciousness raising through feedback and education methods, catharsis through dramatic relief or corrective emotional experiences, changes in choosing through self or social liberation, conditional stimuli management through counterconditioning or stimulus control, and contingency control through reevaluation of contingencies and its management (35). Later, the feedback and re-evaluation of contingencies processes were consolidated into "self-reevaluation".

Next, we conducted a bibliographic review of the PoC in relation to weight loss strategies and dietary change. Scientific papers published between 1979 and 2014 were reviewed to identify specific PoC for weight loss and/or dietary change. The earliest reference of specific PoC for weight loss or dietary change was from 1985. Two processes were added for weight loss, "substance use" and "interpersonal systems control" (37). During the 80s and 90s, the main authors of the TTM referred to these categories and the core set of PoC for weight loss and dietary change, without adding or exploring new categories (36,38,39). In the 2000s, research on TTM and weight loss mostly used the 10 core PoC, with a few exceptions, such as the development of

[1] To use probabilistic estimations of whether or not a given category is more useful than another, it is necessary to have a measurable space. To do so, a partition is necessary. A partition is a set of categories that guarantee that any event of the phenomena of interest falls in one and only one of these categories.

psychometric scales, which included also "substance use" and "interpersonal systems of control" (40,41). Up to 2016, papers from the main authors of the TTM show the same trend: the PoC were taken as a fixed set of 10 categories, aiming to test their statistical explanatory and predictive power (42). In sum, after 1985, the authors of the TTM performed little research to identify novel types of PoC useful for dietary change and weight loss (43–45). The popularity of the TTM for dietary interventions grew, in part justified by the validation of its predictive power for dietary change (43).

Past evaluations of the TTM framework have concluded that some modifications were needed to apply it appropriately to dietary change (46,47). A systematic appraisal of the TTM likewise underscored the need to explore further refinements to the set of PoC associated with dietary change (48). Unfortunately, the most recent systematic review on the pragmatic benefit of using the TTM for dietary interventions did not focus on PoC, just the stages of change construct (49).

Despite these critiques from other scholars, the PoC represented the best initial set of categories to classify psychological change strategies. Since it is based on a multi-theoretical view of psychological change; it enables a theory-agnostic analysis of positive outliers of weight loss. Furthermore, the PoC are located at a level of abstraction between techniques for behavior change and specific theoretical constructs. It is possible to use PoC categories to map novel strategies, without relying on a specific theory of behavior change.

Participants and sampling strategy

This study utilized a set of 59 in-depth interviews with successful cases of weight loss maintenance obtained from a previous study done during 2009 at the University of Pennsylvania by Sciamanna and others (50,51). A case of successful weight loss maintenance or positive outlier was defined as an adult who has purposefully lost at least 30 pounds and has kept them off for at least one year, similar to the definition used by the National Weight Control Registry (NWCR). In the initial study, participants were recruited in the USA via newspaper and online advertisements, describing the nature and inclusion criteria of the study (50,51). A total of 1165 potential participants were identified. After screening and verification of inclusion criteria, 61 cases were interviewed. The initial analysis of the interviews focused on identifying the kind of practices that POs had at the nutritional and physical activity level. The findings suggested POs utilized dietary strategies such as calorie counting, increased consumption of vegetables, replacing caloric content drinks, avoidance of sugars and highly processed foods; and adding both leisure and non-leisure physical activity to their daily routines. The purpose of this analysis is to further explore POs strategies to adhere to their new dietary practices, an analysis at the psychological level.

Interview guide

In the original study, interviews with POs were performed by phone with a thematic guide for interviewing. Participants were asked about their motivation, the strategies and daily practices used to sustain their weight loss. The guide included the themes of dietary, physical activity and weight monitoring practices. Participants were asked about why, when and how they performed these practices; what obstacles they encountered and what

strategies they used to overcome them in the long term. Participants were asked about their initial motivation, their daily routines and strategies, *how* they performed each strategy. Additionally, they were asked to select one of these strategies as a recommendation to others who wish to achieve similar weight control. In total, around 90 hours of interviews were professionally collected and transcribed verbatim. Three expert reviewers checked the accuracy of transcripts with the original audio files.

Analysis

The focus of this paper is on *how* the already identified dietary practices (50) were performed and adopted; that is, in the psychological and practical strategies adopted to sustain them over time. For the purposes of this study, a dietary practice is understood as an abstract unit of analysis composed of a dietary goal, i.e., to eat low fat protein sources, a set of dietary behaviors such as obtaining, preparing, serving and ingesting a chicken breast slice, and a set of cognitive and perceptual processes that are supplementary to those behaviors and goal (52).

With this focus on *how*, a new analysis of the interviews with a deductive-inductive approach (53) was performed. During the deductive approach, the different responses describing how each dietary practice was performed and sustained over time were first coded into the core set of 10 processes of change (PoC) from the TTM (Table 1). During the inductive approach, this set was modified and expanded as needed, drawing from TTM studies and other disciplines such as economics and operations research. Whenever a participant's description of a practice included psychological strategies that did not fit any of the core set of PoC, chunks of text with similar thematic content were grouped, with the aim of creating a new categorical concept. The text chunks were recursively analyzed until a concept was formulated. The aim was to create a new, well-defined, discriminative category of a process of change. Unlike other approaches, where *theoretical saturation* is the aim (54); our aim was to arrive at a set of exhaustive categories to describe properly all the reported strategies. This approach is based on principles from probabilistic theory; future uses of this classification system would be quantitative. Interviews were coded using MAXQDA software version 11 (55).

Ethical considerations. The institutional review board at the University of California, Berkeley, approved the research protocol for this secondary analysis of anonymous data. Data collection was done with the approval of the corresponding committee at Pennsylvania State University (50).

Results

The amount and duration of weight loss of the PO participants deviated significantly from the average weight loss trajectories (Figure 1). Median weight loss of participants was 55 lb. and median maintenance time was 35 months. Average participant age was 41 years and their median weight at time of interview was 155 lb. Seventy-two percent of participants were women; 79% were White/Caucasian; 90% had at least some college education; 52% reported their health to be "fair", 97% lost all or most of their weight intentionally; and about 50% of them were single, widowed or divorced.

This process to more precisely define successful strategies of POs increased the set of categories from 10 to 19 PoC categories. Table 1 presents their frequency and definitions congruent with this analysis, along with a reference to the publication where they were first described. It is worth mentioning that the definitions of the previously reported categories of *stimulus control, substance use, cognitive reevaluation of contingencies and interpersonal control systems* required a more strict definition than those suggested by the main researchers of the TTM (56,57). These stricter definitions were done by rolling back to previous TTM definitions (9,34,58) and keeping the original scientific meaning of the word (i.e. *stimulus control* refers only to the manipulation of external stimuli, not to the manipulation of any environmental factor).

The five new categories of processes of change are: *transactional cost, social support, lead time, object use and bio-rhythm synchronization*. Below we describe the eight most frequent categories of PoC found in the corpus of the interviews.

Feedback

This category refers to those strategies that are based on providing information about one's behaviors. This feedback can come from automated systems, oneself or from other persons. The most reported feedback strategies are self-monitoring strategies were food journaling and calorie counting. Food journaling is mainly used to increase awareness of the frequency, type and amount of food a person eats. The typical recommendation is to write down every food or beverage that is ingested, so one can estimate overall caloric intake. POs reported that they developed their own styles of following this advice and their own perceptions of its value. For example, the sole act of writing down things helped them to become more aware of how much they had eaten.

> "What I would say to someone who is doing a calorie counting method is to write the food down as soon as you eat it, even if you don't write it down in the same book or even the same piece of paper, but just writing it down somewhere on a piece of paper. Sometimes I would have 3 pieces of paper and have to add them all up but just the act of me writing it down helped me remember the numbers and helped me remember what I ate so I didn't forget anything."

While food journaling might be enough to achieve awareness of the food that is eaten, calorie counting has the goal of ensuring that an effective caloric balance is maintained. Although there is enough measurement error in calorie counting to make it an unreliable measure of true caloric intake, POs found it useful for restricting their dietary intake. They also described how calorie counting could be improved, to become less cognitively burdensome.

> "I tell people if you are going to count calories, that's hard. I "minus" calories. I start out with so many calories and I minus what I am eating instead of counting calories. Because if you do it the other way, you are really adding more, but if you count backwards then you can say "this is how many calories I have left to eat."

POs reported that this process becomes less demanding over time, making it easier to perform.

> "I don't physically count calories. I mentally count calories now because when I see food now, from so many months of writing it and calculating and measuring and all that, I see calories. If I go to a restaurant, I think, "Okay how many calories did I already have? How many calories do I have now?" So, when I order from a menu, I order something appropriate for what I think in my mind I have left."

Stimulus control

Stimulus control refers to how people manage stimuli that trigger either the problematic or the desired behavior. POs employed strategies that aimed to modify the perception of negative and positive stimuli.

Limit the amount of unhealthy [visible] food in your home. A common recommendation in health psychology refers to the elimination of negative stimulus and triggers from your environment. POs reported changing their home food environment so that food stimuli are reduced or negligible.

> "I've started baking cookies for people to eat. I'll bake a batch of cookies and stick them in the freezer immediately and keep about six out for us, and that's enough. I'll put them in the freezer immediately… Baby steps. Out of sight, out of mind."

Contingency management

Contingency management is defined as the manipulation of the effects (positive or negative) of the behavior. More specifically, it refers to external reinforcers. In general, POs described using mostly positive reinforcers for their new dietary practices.

> "I try to reward myself with things other than food. Maybe I'll buy something new to work out in or a new video to work out at home."

A particular reinforcer was the use of visualizations, which can especially useful when the benefits of the new practice are not immediately tangible.

> "I imagine how I will look if I follow my dietary and physical activity plan."

Transactional cost

In dietary change settings, we define transactional costs as the effort in time and resources to perform a dietary practice or dietary behavior, except the actual cost of food. This concept includes the cost of searching, evaluating, negotiating and transporting the desired foods. They include informational costs regarding the identification and comparisons of food choices, contexts and providers.

Adherence to the new dietary practices implies the omission or cessation of older dietary practices. For example, given when a person gets hungry at home, what will she/he choose and eventually do? There are several alternative dietary practices. It seems that increasing the transactional cost of performing older dietary practices *relative* to the cost of performing newer ones plays an important role in adherence. The absolute transactional cost seems to be less important than its relative cost to alternatives. For example, one PO said that the reason he decided not to store his favorite junk food at home was because:

> "…the chances are less that you'll eat something really bad for you if you have to get in your car and go buy it in the middle of the night."

> "…I always have some [pure water] to drink next to me at all times."

Manipulating the cost of obtaining foods can also work outside the home, like managing the food environment in one´s car. For example, already having food in the car makes it automatically more expensive - at least in terms of time - to get other items from the food environment.

> "Yes, for example, because I am riding in the car today I have a big bag of grapes with me and I just munch on them."

Cognitive reevaluation of contingencies

This strategy refers to a person's reassessment of the contingencies (effects) of their actions. In contrast to other strategies that focus on changing the effects of the dietary behavior, this strategy does not change anything externally. Rather, it changes a person's internal valuation of the effects of a dietary behavior.

> **Eat plenty of fruits or vegetables.** "…I do that a lot because they are all considered free foods so you can eat as much as you want. And I do enjoy them now. I didn't before, but I do now."

The person's referral to a reevaluation of the experience of eating fruits and vegetables could contribute to making the practice more stable, by being resilient to external environmental changes or a tendency to relapse if the person were to continue with a negative view of eating fruits and vegetables.

This strategy could be also applied to support people to reassess stimuli and behaviors that previously jeopardized their weight control. For example, a participant reported no longer appreciating the effects of junk foods.

> "I wasn't feeling too good after drinking a lot of high sugar drinks. I was feeling sluggish, run down."

> "When you start eating fresh foods, fruits, vegetables, meat, organic meat, and things your taste buds kind of evolve and you learn that. Fast food – that

is another thing I can't eat. I don't even like the smell of going by [a commercial fast food store]. To me that is offensive."

We also found that the cognitive reevaluation of contingencies was also sometimes linked to a self-revaluation process.

"I guess I really just have to say to myself, I don't want to be the way I was. It has to be a real cognitive thing if I don't want to do this."

Object use

This strategy refers to the use, acquisition or modification of objects in order to improve dietary practices. Two key practices emerged in the study findings: "control your food portions" and "write down what you eat and drink".

Control your food portions. Monitoring food portions is a cognitively strenuous task, since one has to assess the size of the food portion just before eating, such as by weighing it. POs reported adopting simpler methods to control portion size. To do so, they performed changes to their environment to make portion control easier. One of them was the use of specific objects.

"I studied as an undergrad abroad and the proportions that my host mother would feed me was significantly smaller than the amounts of food that I was used to eating in one sitting here in the States. So, I was used to large plates and filling them up and heaping over with food and she would serve food on, which were almost similar to saucers and I saw how I was so filled. So when I came back to the States I started to do [use smaller plates] that."

A similar response from another PO:

[Tell me more about how you control your food portions…] "I use the smaller plates and I think that helps a lot…"

"I probably first started slowing down on what I ate. I had smaller meals and I bought the smaller plates and as that started to show a little progress, that's when I started to try to be more active outside."

Write down what you eat and drink. Using specific objects can also improve self-monitoring practices. In this case, the PO's use of specific objects reduced the effort it took to self-monitor their food intake.

"Keep a little pad of paper with you at all times and maybe even keep a little calorie chart with you to make things easier. I had a little purse sized calorie counter for most regularly eaten things."

But such strategies can become even more effective with a specifically designed object for self-monitoring. This PO's recommended a way to reduce the time and cognitive burden of self-monitoring:

> "One of my advices would be to get a notebook with the date in it and maybe the time. Sort of like those daily notebooks where it's a calendar and notebook all in one. So, you'll have the time on the left side and then the date at the top and then you can just fill in what you're eating for breakfast…That's something I should have got but, I didn't think of it at the time. I just got what was cheap."

Another way in which objects can play a role different than changes to stimuli or reinforcement is exemplified by the use of 100 calorie packages. Food journaling and caloric counting can become less taxing by buying pre-measured portions of food.

> [the 100 ca packages] "they are real good, because you are only eating 100 calories. It helps to count calories because then I know I can have cookies because I know they are 100 calories. If you eat two cookies out of a regular pack, two cookies are 170 calories, so you know it does help to have it portioned in a pack."

Social support (other)

In this study, we also found evidence that POs use certain types of social support not covered by any of the initial 10 categories of PoC. The core set of PoC contains a category called "helping relationships". It was originally defined as "empathy and openness to discuss, share and solve problems" (Prochaska and DiClemente 1985), which resembles what happens in professional psychotherapy.

POs described other ways in which people enabled them to sustain dietary change, like instrumental support (sharing the burden of some task, like cooking special meals) and a sense of changing together. Since these types of support are very specific and go beyond the definitions of the already available categories, we decided to create a category for these other kinds of social support.

Many POs referred to having the support of someone in the household, with whom they share the motivation, burden, tasks and a sense of changing together.

> "I belong to [commercial support group] and attend weekly meetings… I have support from my husband. And my daughter is also following the plan as well. So, we kind of support each other."

> "I did [commercial support group] with my husband. He actually signed us up together, so we did it together. It was pretty easy having the person that you live with doing it with you."

Lead time

In dietary settings, we call "lead time" the delay that exists between the initial thought of wanting to eat and the time when food is actually ingested. The eating process could be divided into four main stages: obtaining, preparing, serving and ingesting food. Modifying actions in one or more of these stages can reduce lead time, and executing these stages in advance can also reduce it. For example, a common pattern among POs is to prepare food several hours or days before a meal episode. In this example, the person has the practice of eating whole grains as a breakfast:

> "In the winter time, I use the steel cut oats, which are the cheap bulk kind that are just horse's oats cut up and I cook those, get them up to boiling, turn it off immediately, go to bed, get up the next morning, and I eat half of them the one morning and I put them in the fridge and I eat the other half the next morning and do that again."

Taking advantage of lead time strategies seems to help people avoid falling back to previously less effective dietary practices, i.e. eating flour products such as bread. We found that POs reported using advance thinking and preparedness across many healthy dietary goals, such as increasing intake of whole grains, fresh vegetables, and healthy snacks.

> "Another good tip is to have fresh vegetables cut up. You have it with a little bit of ranch dip and it is already available."

When POs were asked what advice they would give to others who would like to be successful at long-term weight loss, several gave recommendations that fell in the category of lead time: "plan at home what you are going to buy", "do your grocery after having a meal", "buy premeasured foods", "cook a big portion of a dish on the weekends and freeze it for the week" or "prepare your breakfast the night before".

Bio-rhythm and body manipulation

The remaining new PoC is "bio-rhythm synchronization". Though barely mentioned, the category was created aiming to satisfy our criteria of exhaustiveness. It refers to the synchronization of dietary behaviors with biological processes. For example, this person reported a feeling that the body wants or expects to eat or to do exercise at the same hour everyday, and this makes it easy.

> Having a schedule and sticking to it. In regards to both eating habits and fitness habits. …Your body gets used to stuff.

Comparison of strategies used for long-term weight loss maintenance versus initial weight loss maintenance

To explore if the strategies reported by PO vary according to their time in maintenance, we estimated the odds of reporting a specific PoC among those in maintenance for more than four years versus those for one and two years. Table 2 shows

the odds ratio for each PoC category. Each participant could only be counted once per PoC category. Those with more than four years of weight loss maintenance had greater odds of using transactional costs, lead time, substance use, stimulus control and helping relationships strategies than those with two years or less of maintenance. Those in the initial two years of maintenance reported more use of contingency management, consciousness raising and other forms of social support.

Counterintuitive to the generalized public health advice in North America, long-term weight loss maintainers seem not to rely heavily on strategies related to consciousness raising and caloric counting. For example, the person with the largest time in maintenance, 20 years and 60 pounds less than his maximum weight, did not report any caloric counting or weight monitoring strategy. Instead, to keep a fair caloric intake he relies in strategies like "eat the same every day" which imply a great reduction in the cognitive effort and overall transactional cost compared to systematic counting of calories. He also monitors his body mass through clothes, rather than scale.

Use of routines and habits, strategies closely related to reduction of transactional costs, are fairly prevalent among long-term weight loss maintainers. However, for long-term weight losers, routines are not permanent. An outlier recommends enjoying those moments when one goes out of script. "If they [people aiming to maintain weight loss] are going to go out and have dinner, relax and enjoy. I just say go with the flow".

Another theoretically counterintuitive finding is that some people have changed their food preferences on a stable way, enabling permanent change of dietary practices. A case with more than 10 years and 80 pounds less than her maximum weight reported how changes in taste buds occurred after banning all processed foods, leading to a stable cognitive re-evaluation of contingencies: "When you start eating fresh foods…your taste buds kind of evolve and you learn that… [for example] fast food – that is another thing I can't eat".

Discussion

This work contributes to the limited literature on participant-generated strategies for psychological change related to diet and weight control. Given that existing psychological frameworks have not usually been predictive of successful weight loss maintenance, we chose to work with successful positive outliers (POs) as a way identify new strategies and deepen our understanding of how these strategies are used in real-world contexts—rather than proposing investigator-defined hypotheses to test. Focused on the dietary practices identified in a previous analysis (50), this approach identified 5 new user-reported strategies spanning a wide array of techniques from people re-evaluating their dietary habits, to self-monitoring food intake, to creating practical, clever ways to anticipating and overcoming stimuli and behaviors that could jeopardize their weight maintenance goals. In our view, these additional user-designed categories significantly build out the original TTM strategies and respond well to scholars' past critiques that the TTM PoC related to long-term dietary change needed to be improved.

Although weight control studies (19,59) have found that it can become easier over time for people to perform new, healthier behaviors, there have not been adequate explanations for that finding. Results in this study suggest that as the effort of performing the old practice increases, the effort to perform the new one decreases, or both. For example, participants reported that once they got in the habit of pre-cooking healthy foods and/or keeping to certain portion sizes, it became easier to keep to that practice than to go out and purchase junk food. In behavioral economic terms, this means that the effort or cost of performing the new practice is lower than the older, previously preferred, practice. As prospect theory would describe, the perceived utility is relative to an anchor point; in this case the perceived utility of the previous practice (60). This suggests that manipulation of the transactional cost and of the lead time in a healthy practice could lead to perceptions of reduced effort.

There seem to be suggestive differences in the use of several PoC between early and long-term weight loss maintainers. According to some studies, after four years, weight loss maintenance becomes mostly stable (6). Assuming a completely random distribution as the null hypothesis, our results suggests that there are differences on the type of strategies utilized by those with less than four years in maintenance (Table 2). Those in WLM for more than 4 years seem to report more re-arrangement of objects, lead time and transactional cost, a modification of stimulus and report less consciousness raising, contingency management, and other types of social support. These differences might suggest a reliance on environmental factors, as opposed to intrapersonal factors. Aside from social desirability and measurement biases, there are other considerations that hinder our ability of such conclusion. For example, it might be that the differences are random and do not reflect any deeper meaning. On the other side, both groups are not comparable; it is unknown if the early group will achieve similar weight loss maintenance time. Further research could elucidate whether or not these differences on frequency of use of PoC are meaningful.

Naturally, due to the sampling nature of this study, this observation is not representative of the larger population of people aiming for WLM; they only represent a hint at what to explore in experimental studies.

In addition, participants mentioned that, as they practiced healthier food behaviors over time, their food preferences began to change—making it easier for them to stick to the new approach given that they no longer liked "junk food". This finding was illustrated by the category labeled "cognitive reevaluation of contingencies," meaning that if you put the same person in the same context with the same food choices, they might choose differently after using this strategy. In essence, it suggests that people's food preferences can change. This runs counter to one key assumption of traditional economic theory that assumes that people's preferences are constant (61). If they are not, then economists might need to draw on behavioral economics models that consider this phenomenon, i.e. proposals made by Tversky, Kahnemman and Rabin (60,62).

Overall, this study provides new insights into strategies to promote weight control. Further research is required to test the effectiveness of these strategies compared with prior proven weight loss maintenance interventions, such as the Look AHEAD trial (63,64)

Limitations

This study has limitations. It is a qualitative study of participants drawn only from the US population in 2010; so the findings of this study cannot be generalized beyond this population. For example, at the time of the original selection of the participants, the official recommendations for weight loss were to follow a low-fat diet, with daily, moderated caloric restriction. The most popular weight loss strategy was to monitor food intake through caloric counting. These factors permeated the interviews in this study in which participants made multiple references to them. Participants did not mention more contemporary dietary advice related to intermittent fasting, time-restricted eating or low-carb diets. Further, the interviews provide self-reported strategies rather than observational data such as photos or videos of participants' food consumption or various weight loss strategies.

However, the primary strength of this study is that it used the innovative approach of going to those positive outliers who represent the relatively small proportion of the population who have actually successfully maintained weight loss for 1-20 years. Given that "theory-driven" interventions to help people maintain weight loss have shown disappointing results overall, it is critical to drive theory change with evidence from new, effective real-world strategies from the users themselves. The value of this approach reflects over 50 years of research about the effectiveness about participatory design to build theory and interventions. This study contributes to the limited literature about strategies for successful weight loss maintenance and the importance of research methods focused on positive outliers. Future research is needed to build out successful weight control strategies and integrate them into practical interventions.

Conclusions

Prior weight loss maintenance interventions have shown disappointing results. This study suggests new categories of psychological strategies to achieve long-term dietary change. These findings, supported by newer concepts from disciplines, such as behavioral economics and operations research, bring fresh ideas for the development of dietary programs and policies. A key conclusion is that to advance psychological change strategies, it is necessary to address the relationships between aspects of the environment, behavior and cognition (65,66). The new set of categories identified in this study of psychological change contributes to this goal. To our knowledge, this is the first qualitative study to compare the strategies of long-term weight loss maintainers (four years and more), versus strategies used in the initial period (up to two years). Together, our findings suggest that long-term weight loss maintainers shift away from cognitive-attentive strategies—such as caloric counting or nutritional labeling—to an ensemble of contextual and, possibly, habit and routine formation strategies (67–69) which in turn support bio-rhythm synchronization. Experimental studies and statistical analysis are needed to explore this type of interaction among behavioral and physiological processes. It would also be useful to replicate this work with a more diverse sample within the US as well as in other national contexts. Future work should also explore how people use some

of the newer approaches to achieving and maintaining weight loss, from novel nutritional approaches to the use of novel technology-enabled tools.

Based on the detailed findings of positive outlier participants in this study, our perspective is that the "solution space" for long-term weight loss solutions is richer than what has been proposed based on previous theoretical approaches. Theories of behavioral change that dominate the field appear to focus excessively on individual rather than contextual factors. Further research could further explore which of these newly proposed categories have the potential to improve long-term effectiveness of weight-loss and weight loss maintenance interventions.

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Table 1. Processes of change associated with dietary change under a condition of a reduced weight.

Freq	Process	Source	Definition
35	Feedback	Core Set	Those consciousness-raising strategies that are based on providing feedback about one's behaviors and self. Originally, they were thought as coming from a therapist in a verbal manner. However, this includes any sort of informational loop that feeds the consciousness of the actor.
26	Stimulus control	Core Set	Processes that manipulate the prevalence and perception of stimuli associated with conditioned responses.
22	Contingency management	Core Set	These processes focus on the manipulation of the effects (positive or negative) of the behavior. In strict meaning, it refers only to the external reinforcers of the response (intrinsic reinforcers are usually not manipulated under this umbrella).
22	Transactional cost*	New category	The effort in time and resources to perform a dietary practice or dietary behavior, except the actual cost of food. This concept includes the cost of searching, evaluating, acquiring and transporting the desired foods. They include informational costs regarding the identification and comparisons of food choices, contexts and providers.
20	Reevaluation of contingencies	Core Set	Cognitive processes that modify the internal value or appraisal that one puts on specific or concrete contingencies. It involves usually a change in values, criteria or preferences, so the appreciation of such contingency changes. It is important to note that most economic theories require the assumption that this internal appraisal is constant and steady.
19	Object use	New category	The use, acquisition or elimination of specific objects in order to perform a given behavior or practice
15	Social support (others types)	New category	Under this category we classify resources that support psychological change and are based on social ties. We include three types of support here: instrumental (practical support to perform the dietary behaviors or achieve dietary goals), motivational and have a sense of belonging (when a person teams up with another person, sharing same psychological change goals).

… continuing Table 2

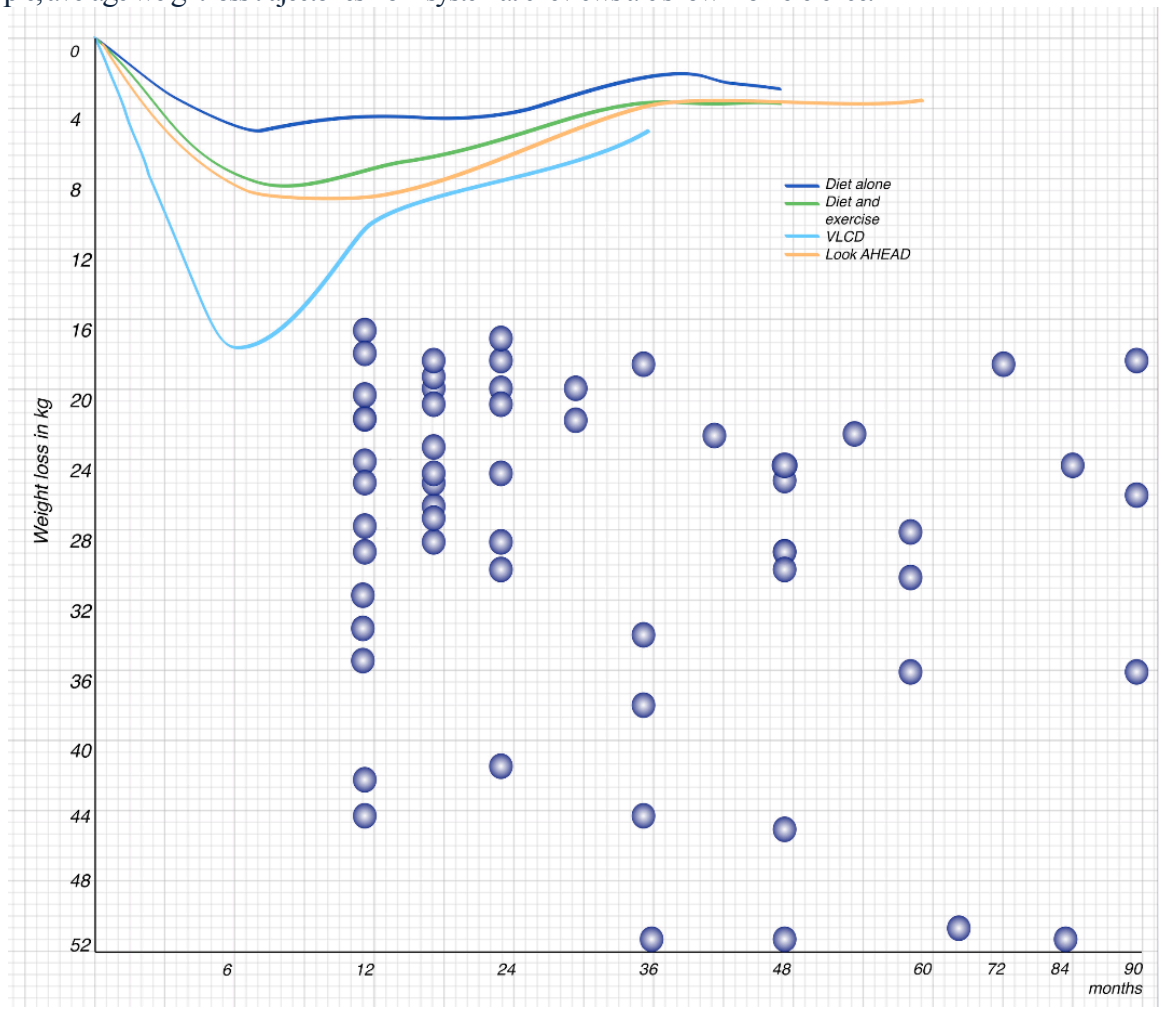
14	Lead time**	New category	Manipulating the delay that exists between the initial thought of wanting to eat and the time when food is actually ingested. The longer, the less likely to pursue the intake of such foods.
12	Interpersonal control systems	Prochaska et al, 1985	It is another type of social support. Originally included only the use of social pressure to perform or not a given behavior.
11	Counter conditioning	Core Set	The replacement of responses associated with a stimulus by new ones.
10	Corrective emotional experiences	Core Set	Those cathartic processes that are based on a personal experience in order to generate the catharsis
10	Helping relationships	Prochaska et al, 1985	This process refers to those interpersonal relations that offer empathy and openness to discuss, share and solve problems.
9	Social liberation	Core Set	Self liberation processes that are started by external, social factors. Eventually, they end breaking limiting mental models and increasing one´s ability to choose new ways to behave and be.
8	Substance use	Prochaska et al, 1985	Processes associated with the use of substances (i.e. drugs, foods and drinks) in order to modify or perform behavioral responses
8	Bio rhythm synchronization	New category	The synchronization of behaviors with biological patterns of activity. For example, matching food intake with circadian peaks of insulin sensitivity.
2	Self-liberation	Core Set	This processes refers to the liberation of oneself, through the acknowledge that one´s nature is basically free to choose, generate and acknowledge new ways to behave, rather than sticking to the problematic behavior
2	Environmental reevaluation	Core Set	The re-appraisal of the physical, organizational or social environment and its influence on one's behaviors.
1	Dramatic relief	Core Set	A cathartic experience triggered by an artistic expression, typically a film or a reading.

* This definition is a derivate of a concept from behavioral economics.
** This is a derivative of an operations research concept.

Table 2. Prevalence of PoC between medium and long-term weight loss maintenance

Process	More than 4 years with weight loss (N=16)	Less than 4 years with weight loss (N=43)	Odds Ratio
Feedback	5	14	0.94
Stimulus Control	7	10	2.57
Contingency management	2	7	0.73
Transactional cost	8	8	4.38
Reevaluation of contingencies	5	11	1.30
Object use	6	9	2.27
Social Support (other types)	2	8	0.63
Lead Time	6	4	5.85
Interpersonal control systems	3	7	1.19
Counter Conditioning	3	6	1.42
Corrective Emotional Experiences	0	0	NA
Helping relationships	4	5	2.53
Consciousness Raising	1	5	0.51
Social Liberation	2	5	1.09
Substance use	3	3	3.08
Bio rhythm synchronization	0	1	0.00
Total participants	16	43	59

Figure 1. Amount of weight loss (vertical axis) and maintenance time (horizontal axis) of the interview sample; average weight loss trajectories from systematic reviews are shown for reference.



Note: X-axis was shortened; maximum weight loss maintenance was 20 years.

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Chapter 3. The Dietary Intervention Canvas: a Health Intervention Design Method for Translational Research.

Abstract. A nascent type of dietary intervention strategy is grounded in translational and design sciences. Unlike old style interventions, typically based on the distribution of standardized diets, food vouchers, pills or a food pyramid, dietary interventions should focus on causal mechanisms and the holistic experience of the end user. This paper presents the Dietary Intervention Canvas (DIC), a method that combines principles from nutritional, behavioral and design sciences to develop improved dietary interventions.

The method. The DIC consists of a canvas (blueprint) and six design processes. The canvas provides a matrix to integrate findings and to define intervention components. The elements of the canvas are: causal mechanism, medical nutrition therapy specifications, target population, and value proposition. Another five elements are based on the eating phenomena: obtaining, processing, ingesting, post-ingesting, and fasting stages. The six design processes are: understand, observe, ideate, build, test and iterate. These processes blend to generate two main cycles of development: the problem space and the solution space.

Discussion. The DIC improves the design of dietary interventions by streamlining the path from metabolic and dietary research findings to specific dietary interventions. It incorporates key principles of design sciences to improve the effectiveness of the final intervention prototypes. Rather than trying to replace current planning processes, the DIC enhances current health planning efforts. It empowers intervention designers to develop novel intervention concepts. The DIC also enables communication and sharing of design findings among designers, implementers and end users by using the canvas as vehicle for communication. **Conclusion.** By using essential principles of design sciences integrated with other intervention planning methods, the DIC aims to empower health researchers and practitioners to develop more effective interventions.

Introduction

For many centuries, dietary factors have increasingly been considered a pillar of human health. They are addressed by most major health organizations (1–3) Despite scientific findings and a long history of intervention efforts, most population dietary goals have not been achieved (1–3). As our understanding of genomics and metabolism has advanced, it has become clear dietary interventions not only are critical for maintaining health, but can outperform pharmacological interventions for certain diseases (4,5).

For the public health field to take advantage of such important findings, better translational methods are needed. There is growing interest in and guidance about incorporating design science principles to improve the effectiveness of dietary interventions (6) (7,8). Design sciences encompass a wide variety of disciplines that are engaged in the creation and manufacturing of novel products, objects and solutions such as in architecture, engineering, computer science, and artificial intelligence. Because applying design science has been shown to improve the performance of interventions and programs across such a wide range of disciplines, it is surprising how little the public health community (and the nutrition community more specifically) has embraced these methods in its work. One barrier is the lack of a framework to guide the incorporation of design science methods into dietary intervention planning.

The aim of this paper is to describe the Dietary Intervention Canvas (DIC), a new design method explicitly developed for dietary interventions. It incorporates principles from design sciences and current health planning frameworks to empower teams of health, behavioral and social science researchers, practitioners and end users to develop more effective interventions. It is intended to reduce intervention failures through more careful, iterative design—or in the words of Peter Skillman: "Enlightened trial and error succeeds over the planning of the lone genius." (9)

Strengths and weaknesses of health intervention design methods

For the development of dietary interventions and programs, public health practitioners rely on design methods from within the field of health promotion. This field has established a good foundation of integrated theory and methods to guide intervention development such as epidemiological analysis, community-based participatory research, and behavioral and organizational analysis (10–13). For example, the multidisciplinary PRECEDE-PROCEDE framework integrates multiple levels of analysis and planning (10). This method has been applied to a wide variety of health interventions in diverse global contexts for over two decades (14). It has been praised for its integrative view, encompassing not only epidemiological knowledge but also taking into account community and organizational factors. The model is also versatile. While an ideal implementation of all its steps requires significant resources, it can also be implemented in a streamlined way in lower resource settings. The Behavior Change Wheel is another implementation sciences model that can be used to develop interventions that require behavioral change from the population (15). It

proposes an analysis at the personal, organizational and policy levels. The model aims to offer a comprehensive perspective of the different ways an intervention can influence population behaviors.

Despite the overall value of these models, they are also quite general. Their intervention design guidance is generic for all areas, whether for developing a vaccination program, a mammography screening campaign, or a nutrition intervention. This general purpose becomes a weakness when facing complex targets, such as changing sexual habits or dietary practices. For example, dietary practices are complex phenomena involving physiological, behavioral, social and contextual components. Without proper frameworks for analysis of dietary practices, health intervention designers might not identify great leverage points to catalyze dietary change. Worse, health intervention designers might get lost in this complexity of dietary practices, yielding an intervention that completely miss the target physiological mechanism of dietary change. Given the poor performance of past dietary interventions, we propose a new dietary-focused method to help health researchers and practitioners navigate this complexity and create more effective interventions.

We also note that none of the currently popular intervention methods significantly integrates specific principles from design sciences (10–12). We conducted a systematic bibliographic review to identify methods to develop health interventions that mention design sciences or design thinking principles. Three methods that incorporated design principles were found; all three focused on developing eHealth and mHealth interventions and had a strong engineering focus. Initial utilization of these methods seems to have shown positive outcomes on e-health interventions (16–19). However, there was little mention about how to incorporate them into current methods to design and plan health interventions and programs (such as PRECEDE/PROCEDE, CBPR or Behavior Change Wheel). Another limitation is that none of these design science-focused methods was specific to dietary interventions.

In light of these findings, we identified the need for a new method that would incorporate design science principles into health intervention planning and that would focus on dietary interventions.

Principles of design sciences

Before discussing what design sciences are, it is useful to set forth how some terms are utilized in this document. A "method" is the means to achieve a certain goal, i.e. produce scientific knowledge (20). Following its etymological meaning, methodology is the study of methods (from the Greek, *logos*, path or study) (21). Finally, "thinking" is a mindset, an attitude. Therefore "design thinking" is the mindset of designing. The term "design thinking" has been popularized and widely used by the design school of Stanford University or "d.school" [www.dschool.stanford.edu].

Broadly speaking, the design sciences deal with the development, production and revision of human-created entities, objects or phenomena. They deal with the creation of the "artificial" (22), such as: objects, buildings, computer applications, programs (including health interventions) and learning environments. Gregor characterizes the design sciences

as the 3rd branch of scientific inquiry; the other two branches are the natural sciences (such as physics and chemistry) and the human sciences (such as anthropology and other social sciences) (23). For this reason, the design sciences provide important theoretical and methodological guidance to complement those in the natural and human sciences.

Design science theory and methods contrast in important ways with those of the other branches of scientific inquiry. From an epistemological point of view, design sciences focus not on "what is, but what can be" (22). For this reason, design sciences offer the best approach to "study the future"—such as the development of a new intervention, whereas the natural and human sciences are focused on the study of existing phenomena. Without design science approaches, researchers and practitioners have traditionally over-relied on reviews of past scientific literature, rather than take advantage of powerful design methods that begin in the present and move into the future.

Design theorists have distilled a set of principles to practice "evidence-based" design, by analyzing how different design disciplines, such as engineering, computer systems, artificial intelligence, architecture and urban development tackle complex or "wicked" problems (22,24–26). This concept is important because it underscores the impossibility of fully understanding a problem before solution generation begins. This can be contrasted with the traditional, but weaker approach of investigators who define problems using only findings of past studies and pre-design interventions to address those problems before an intervention project begins (for example in a grant application) and then keep the problem definition and the intervention design fixed even as more information becomes available. Design science theory and methods explain the drawbacks of this approach and the value of using more iterative, forward-oriented design methods.

In our review of design science principles, we suggest that the following have particular relevance to designing health interventions:

1. Design is an iterative process of problem definition and solution development

Because design science theory is based on the premise that problems cannot be well understood until a solution generation process has begun, a core principle is that design science methods are highly iterative and recursive. Figure #1 illustrates a useful conceptual model of the design process in which problem definition and solution generation take place gradually and simultaneously. The figure is based on previous analyses from other theorists (26,27). As problems are identified, they lead to suggestions for solutions to address them. Likewise, as solution ideas are created and tested, they lead to the refinement of problem identification, including the identification of new kinds of problems. The "problem-solution" process is pursued until a prototype is generated that meets goals (specifications) identified for the solution. This is a trial and error process; a related maxim of the design community is to *fail faster, fail cheaper(28)*. This approach to seek and learn from "small failures" at the outset can avoid the "epic failures" that we often see in disappointing results of more traditionally "expert-designed" health intervention trials.

2. Modular, functional design

In design, a frequent model of analysis is to break down complex design challenges into manageable ones. For example, Christopher Alexander, an architectural theorist, suggested

that the architectural process (designing buildings and other constructions) is a task that could be split into different functional modules or elements (24,29). The process means defining the function that each module fulfills in the whole design and how each module interfaces with the others. By doing so, designers focus on improving or solving one module or element at a time, knowing that another module's functionality would not be affected, as long as the interface between modules is intact. This approach has influenced the construction of the world wide web, development of most major operating systems and artificial intelligence. A good set of rules (28) to develop such modular designs is to build intervention components that:

a. Do just one function, but do it very well;
b. Are meant to work together;
c. Handle factors that are common across lifespan and cultural settings, e.g. the stages of the eating process.

3. Form follows function

This principle, attributed to the Bauhaus movement of the early 20th century (30), suggests that the design of objects should be first based on their inherent function rather than primarily on aesthetical considerations. The corollary in public health is that the highest priority for a health intervention is to maximally achieve a health goal, rather than to use specific theories or intervention channels. Those issues should be secondary; if a theory or a channel does not help to fulfill the target function, it should be discarded or revised.

The Dietary Intervention Canvas Method

The Dietary Intervention Canvas (DIC) is a method to translate key dietary/metabolic findings into dietary interventions to improve health. The method is composed of a canvas (Figure #2) and six design processes to analyze dietary practices. The method was developed to *empower* scientists to design better interventions by using principles of design sciences along with their health sciences expertise. Instead of replacing them, it adds powerful design science methods to those traditionally used in health planning. The DIC intertwines smoothly with other integrative frameworks for public health planning and implementation science, such as the PRECEDE-PROCEDE model or the Behavior Change Wheel. The DIC is meant to develop supportive interventions, for users that already are determined to solve a health issue.

The DIC can be used in formative research, pilot, and developmental evaluations (31). It strengthens ways to translate accumulated scientific, organizational, social and cultural knowledge regarding the context, the target population and health systems into potential alternatives of intervention.

The first step in the design process is to define the design challenge. It is an actionable definition of the problem to solve in the design process. It can be defined by framing a *question* with elements of the DIC. For example, "How *might* we help [the target population] to trigger [the causal mechanism(s)] to improve [the health outcome]? In addition, all design challenges have some design specifications. The specifications are those characteristics that any solution should satisfy, e.g. characteristics of the target healthcare system, preferences of the target population, cost and efficacy of a given solution etc.

Experienced designers love specifications and constraints, they help them to achieve better performance than without them.

The Dietary Intervention Canvas

A dietary intervention aims to modify complex phenomena related to eating. The canvas is a matrix that enables designers to break down dietary interventions into these functional, mutually exclusive components—simpler, functional elements (see figure #1). The canvas contains an internal and an external level. The internal level supports translation of novel biochemical or physiological findings into medical nutrition therapy specifications, conditional on characteristics of the target population and context. The external level offers a framework to analyze complex dietary practices. It contains the eating stages that are: obtaining, processing, ingesting, post-ingesting, and fasting stages. They provide an instrumental framework to align and organize the diverse spectrum of dietary factors, i.e., economic, cultural, symbolic, physiological, etc. Any of those should converge and influence at least one of these eating stages. This set of mutually exclusive, collectively exhaustive stages was developed to guarantee a 360-degree view of the eating phenomena, helping to uncover leveraging points or novel behavioral intervention approaches.

The DIC proposes a three-way focus to improve effectiveness of interventions: the physiological causal mechanism, the target population and context, and the value proposition of the intervention. The causal mechanism supports a claim of potential effectiveness, since an intervention´s maximum effectiveness is limited by the causal mechanism´s efficacy. The careful attention to the target population and context addresses the fact that effectiveness is conditional on such factors and the value proposition keeps the design team focus on what really matters to the population, avoiding some funder's theorists' or designers' biases towards certain value proposition.

The circular form of the canvas conveys the message that design is a cyclical process. With each cycle or iteration, the odds of discovering important interconnections increase, compared to a linear approach. For example, it might be that the intervention needs to address how the population obtains and chooses food; an educational component could be developed for that end. But after the first iteration, it was discovered that the critical element is how food is processed or preserved; or perhaps the physiological mechanisms cannot be triggered unless the subjects prolong their daily fasting periods. The canvas aims to trigger such sort of findings. Below, the elements of the canvas are defined. Table #1 offers a set of guiding questions to define each of them.

The core level

Causal Mechanism.

The first consideration of dietary intervention planning is to define the target, key causal mechanism to achieve the desired health outcome. Being able to express this causal mechanism in biochemical or physiological terms is a critical step. This mechanism specifies how dietary/fasting factors cause physiological or metabolic changes that, in turn,

affect the health outcome. This mechanism is better expressed in metabolic, physiological or biochemical terms, rather than in behavioral or food terms. For example, rather than saying "consumption of margarine should be reduced to decrease heart attacks", it is better to eliminate the word "margarine" and say: "Consumption of trans fat increases LDL and decreases HDL. This changes, along with pro-inflammatory factors X and Y will increase deposition of cholesterol in endothelial cells; which in turn increases the risk of heart attacks."

During an iterative dietary intervention design process, for each underlying causal mechanism there would be more than one medical nutrition therapy able to trigger it. In turn, multiple dietary practices could fulfill those medical nutrition therapy specifications. By systematically examining potential combinations or families of combinations at these three levels, it is possible to assess which ones are more likely to be effective given the target context and population.

Target population.

From all the potential users of the intervention, the target population is the subsample on which the intervention is focused. In health planning, this definition is typically done with sociodemographic characteristics such as age, sex or education. It also includes some clinical characteristics such as anthropometric, nutritional and biomarker or genetic profiling. Lastly, psychographic traits, such as level of readiness to change or their skill levels to adhere to treatment are also useful.

The DIC emphasizes achieving proper fit between the value proposition of the intervention and the target population. That means that the intervention should address their needs and should be appropriate to their context and the healthcare system in which it is going to be implemented.

Medical nutrition therapy (MNT) specifications.

The MNT specifications detail the medical nutrition therapy that will trigger the targeted causal mechanism. Typically, these specifications contain information on the caloric intake, the ratio of macronutrients in the diet, the micronutrient intake and, very often, the requirement to include or avoid certain types of nutrients (i.e. saturated fat), phytochemicals (i.e. lycopene) or non-nutritive substances (i.e. mercury). An example of MNT specifications is included in the Standards of Care for Diabetes of the American Diabetes Association (32). MNT specifications might also include information about the amount, frequency and type of food to be eaten.

Defining the MNT specifications allows the design team to better analyze the current dietary behaviors of the target population and devise ways to improve them, always with the intent of triggering the target mechanism. A dietary intervention should intervene at some point of the eating process. The different functions a dietary intervention can have are:

- Influencing behaviors to obtain food
- Influencing behaviors to process food
- Influencing behaviors to ingest foods

- Influencing behaviors that occur after ingesting foods
- Influencing behaviors related to fasting

Proper definition of the MNT specifications implies a scientific understanding of how to trigger the target causal mechanism that will lead to the desired health outcomes. We previously noted that a variety of dietary practices can trigger the same mechanism if they fulfill the MNT specifications. For each eating stage, specific goals might exist. In their efforts to adhere to the same MNT specifications and goals of each eating stage, different participants might use different dietary behaviors. For example, a specification might be to decrease the number of calories ingested at breakfast. In a well-designed intervention following the DIC, participants in the target population could do so through various dietary behaviors, such as changing ingredients, cooking methods, and/or reductions to serving sizes.

The external level of the canvas

The external level of the DIC contains the value proposition and the eating process; it focuses mostly on the behavioral part of the intervention. The DIC promotes keeping a 360-degree vision of the eating process to avoid some common mistakes, e.g. focusing on food choice when in fact it is at the "cooking" stage where the key dietary factor resides. This level also works as an interface to the large tradition of sociological and psychological analysis of eating.

Value Proposition

Any proposal of a dietary intervention should offer net positive value to the target population. The potential health benefit is one important component of value, but the net value must consider all of the ways that procuring, preparing, and eating food create value. There may be value in changes to ones appearance and in ability to exercise, but also in being able to eat and drink without restrictions. The target users need to believe that the benefits outweigh the costs if the intervention is to succeed and be maintained. When people decide they want a certain health outcome, they might need to decide among different alternatives to achieve it. Why would they decide to use a specific intervention? How is it better than the other alternatives? A value proposition answers these questions from the point of view of the target population. It is advisable that the design team not rely only on a single parameter, such as a subsidized cost or that an approach is the official intervention from the government to formulate the value proposition; it should be a deep reflection on why it is going to be better than the other alternatives.

In order to define the value proposition, the design team should consider three factors: alternatives, resources and people's preferences. Alternatives refer to the set of choices people have. For example, if the intervention aims to promote weight loss, people might decide to use their usual healthcare services, go to a private medical service, follow the advice they heard on the radio or Internet, or perhaps the friendly tip of a neighbor. They could even decide to do nothing. When choosing among intervention choices, people's financial resources might come into play, as well as the perceived value of each alternative.

In economics, "preferences" refers to latent values with which people evaluate and select among choices. There are two main methods to explore such preferences. "Stated preferences" are obtained by directly asking people what choice among a set of alternatives they would prefer. "Revealed preferences" are obtained by observing actual decisions, either in real life or in experiment with real consequences. Because revealed preferences have real-world implications, they are considered more reliable than stated preferences. For example, the design team might offer some members of the target population solutions A, B, or C, guaranteeing that they will enter into a drawing to win the selected solution. By carefully selecting the defining characteristics of the solutions A, B and C, it is possible to infer people's preferences.

A sound value proposition implies an understanding of the needs and barriers that the population participants face if they are to change behavior to achieve a health goal. For this reason, the value proposition will help to select the best way to address the external levels of the canvas and defining the intervention components.

Stages of the eating process and classification of dietary behaviors.

Eating is a complex phenomenon that spans an array of factors from basic biochemical and physiologic processes to social, cultural and culinary behaviors. Creating a new model to guide dietary interventions requires understanding the behavioral dimension of eating in adequate detail so that their factors can be incorporated into highly specific design science methods as described above.

A review of the scientific literature was conducted to identify methods to define and classify dietary behaviors. Related research and frameworks in health promotion (2,3,33,34), social sciences (35,36) and psychology (37,38) were reviewed. With the exception of pathological eating disorders, we did not find a formal taxonomy for dietary behaviors. Accordingly, we proceeded to formulate our own definition. A behavior is considered dietary if it is directly or indirectly related to the act of bringing food from outside to the inside of the gastro-intestinal tract. The wide variety of dietary behaviors can be classified using five key events during the eating process: having physical possession of food, making food ready to eat or preserving it spoilage, bringing food from outside to inside the body, and handling food, leftovers and dietary tools after ingestion. The set of categories was defined as: obtaining, processing, ingesting and post-ingesting behaviors. These categories reflect the eating process observed across different cultures and stages of the life course.

Obtaining

This category of dietary behaviors refers to the physical acts of selecting and acquiring food items. Food choice and food purchase behaviors are part of this category. Food selection is influenced by a myriad of physiological, cultural and cognitive factors (39) whereas food purchase is a more specific economic behavior especially influenced by availability, convenience, cost and accessibility (40). Examples of behaviors included in this category are: to read (labels or menus) to choose (the place where food is obtained), to compare (two similar food options), to buy, to order, to choose (from a menu), to request

(changes to dishes). It is important to note that if food or ingredients are already stored in the subject´s house, there is already physical possession of the food items. Therefore, any additional dietary behavior falls within the next categories.

Processing

This category includes the physical acts of processing foods so that they are ready to be eaten, such as preparing and cooking. Examples are: to peel [fruit], to clean, to wash, to rinse, to uncap, to unseal, to season, to thaw, to reheat. Within the DIC, the term *cooking* is used in a specific way, similar to the anthropological analysis of Levi-Strauss (35). Cooking is a subcategory of processing and refers to those processes that involve careful manipulation of heat or fermenting processes. It includes brining, fermenting, foaming, whitening, baking, parboiling, blanching, sautéing, smoking, frying, battering, salting and others.

Ingesting

The physical act of bringing food items from the outside to the inside of the digestive tract (including the mouth) is called ingesting. The category includes actions such as: to take to mouth, to swallow or devour, to sample, to taste, to smell, to chew, to suck, to lick. The objective is to satisfy hunger, the desire of pleasant sensations or to fulfill social commitments that triggered the food behaviors in the first place. Serving is a subset of ingesting because it occurs after the food is ready to eat but before the food is delivered to the digestive tract. Examples are dividing, cutting, portioning, arranging, pouring, measuring, and sharing. One of the best reviews on ingesting and serving factors was done by Wansink, although this reference is focused mostly on volume intake (41).

Post-ingesting

This category includes physical actions that occur after ingesting but before the subject gives away or loses possession of the food. They include the acts of cleaning the cooking and eating spaces, storing, discarding or giving away food, and composting.

The eating process stages and their corresponding dietary behavior categories were defined in a way that theoretically makes them mutually exclusive, and collectively exhaustive. Obtaining mediates between not having and having physical possession of food. Processing mediates between food that is not ready to eat and food that is ready to eat. Ingesting mediates between foods that are outside of the digestive track and that which is inside. Post-ingesting completes a set of mutually exclusive categories and covers the dietary behaviors that occur after ingesting and until losing physical possession of food.

Fasting

Finally, although not part of the set of mutually exclusive categories described above, it is necessary to mention fasting. Fasting is the complement of ingesting, it is a period where neither macronutrient nor micronutrient intake occurs. The intake of water without nutrients is allowed. This category was added to complete a gestalt view of eating and because of the

importance of fasting states to generate metabolic changes (42,43). For example, it involves adjusting the meals prior and post fasting, adjusting social interactions and exposure to food stimuli, dealing with hunger, etc. It is therefore important to take into account this physiological state that occurs between dietary stages and the behaviors related to it.

The outer colors of the canvas

The four colors in the canvas represent four types of support that would cover most of the potential scenarios: instrumental, affective, cognitive, and belonging. Cognitive support covers strategies such as providing information, personalized feedback or cognitive therapy. Affective support covers techniques that modify motivation or that support psychodynamic processes. Instrumental support includes any strategy that reduces directly the practical effort of performing the target dietary behaviors such as providing supplements, cooking tools or prepared meals. Finally, belonging strategies are those that make participants feel part of a larger group, goal or mission. While it can be argued that belonging strategies fall within affective support, it is necessary to stress their importance and capability to trigger dietary behavior change. We considered it necessary to set them apart because they are also more subtle to implement than other affective strategies.

How to use the canvas: the design process

Designing is a sophisticated cognitive process that can be represented as two simultaneous and interconnected cycles (Figure 1). The first cycle is the analysis of the problem space—the causal web that generates the problem. The second cycle is the exploration of the solution space—the set of scientifically based solutions that could resolve the problem in real world contexts for the target population. The hourglass icon at top of the two cycles indicates that each of these cycles aims to achieve some balance; they are not meant to run indefinitely (44).

For the problem space cycle, this balance is achieved when it is possible to identify the causal mechanisms that will maximize the probabilities of solving the problem in the specific context identified. This is represented mathematically by the equation and the graphic at the center of the cycle. They represent a structural causal model, embedding the idea that, at least for health issues, one cannot rely on statistical knowledge alone, it is necessary to use causal reasoning (45).

The solution space cycle achieves a balance when it identifies which, among all proposed alternatives of a solution, is the one that maximizes the probability of inducing the target causal mechanism. This is also represented mathematically by the equation at the center (*arg max*). The graphical image at the center represents the progressive selection of ideas and prototypes towards the identification of a few alternatives of solution.

Within these cycles, there are different design sub-processes. The Stanford d.school defines key design processes as: “understand,” “observe,” ”ideate,” and “build and test” (46). These are called “processes” rather than “steps” or “phases” because they often take place in parallel or cyclically, rather than serially (Figure #1). For example, after passing through “understand,” “observe” and “ideate,” the health designer might discover something

that leads her/him to go back to the "understand" process. In turn, this may lead to a different ideation processes and different solution prototypes to test.

To execute each of the design processes, it is necessary to use specific design techniques. A design technique is a specific procedure, a set of actions to achieve concrete goals within the design process. Such procedures might take place at a desk, in a laboratory or in the field. Some techniques are very specific to certain disciplines while others are shared interdisciplinarily. For example, industrial design utilizes *interviews* and *observation* of the target population to understand their needs; architecture utilizes *sketches* to analyze and evolve the spatial design of a new building; software development employs *simulations* to test the performance of a given system. An online repository of design techniques (see: link) has been developed (47) and complements the design process of the DIC.

1. Understand: define a causal model of the health outcome

The main goal of the "understand" process is to develop a scientific model of the health issue by integrating knowledge from basic, health, social, behavioral and design sciences. However, there is an important difference in the design sciences to what is done in natural or social sciences. Rather than an exhaustive review of factors that originated or caused the problem, this design process has a practical focus on modifiable factors to transform the health outcome. In this regard, an important distinction has to be made between preventive and curative interventions. If the health outcome is to prevent a disease, then it is appropriate to focus on what causes the disease. However, when the goal is to "cure" or reverse an ailment, the focus should be on those factors that can reverse the underlying pathologies.

Define the scientific model

The practice of science-based design implies the progressive refinement of scientific models to understand the target issue. In dietary interventions, this causal model can include factors spanning from DNA transcription and translation to physiological, metabolic and genetic expression changes The degree of accuracy of this model is chosen by the design team. The end product is a representation of all potential mechanisms that contribute to a target health outcome. The scientific model should include this information, structured around the elements of the DIC:

- Which causal mechanisms generate the health outcome of interest?
- How are these mechanisms triggered, modified or leveraged by the:
    - type of foods and ingredients utilized?
    - way foods are processed?
    - context, volume, frequency and rhythm of intake?
    - different types of fasting practices?

List target causal mechanism.

Using the scientific causal model, the design team can start to list potential targets of the intervention. Each causal factor can be used alone or combined as a proposed causal

mechanism for the intervention. Sometimes, the causal mechanism would be the replacement of a whole structural causal equation by a specific value. This is often the case when one assumes that a whole range of factors will be neutralized by the intervention, e.g., when subsidies are assumed to cancel out any effect of economic acquisitive power on food selection.

Order causal mechanisms by their importance.

After defining a list of causal mechanisms, it is then necessary to organize them hierarchically with some operational criteria of importance. A standardized method, defined in the epidemiological stage of the PRECEDE-PROCEDE model is to identify their relative influence in the health outcome and the likelihood of changing them in the real world. For that end, a matrix of 2x2 can be used, using a classification of high influence/ low influence and highly changeable/not highly changeable (10). Those factors that are both of high influence and highly changeable, can be then considered the most important to address.

A updated version of such approach, adding a causal and quantitative perspective, is offered by the iPRECEDE (48), which we briefly describe here. First, a structural causal model defining basic relationships among variables should be built. Then, using structural causal equations, an estimate of effect of specific causal mechanisms on the health outcome are obtained. Then, the design team should assess whether or not those mechanisms can be engendered in the real world through known interventions. Using the DIC method, novel interventions can be devised, aiming to engender such mechanisms. For each intervention, an estimate of potential effectiveness can be obtained. This can be done using two values: the probability of changing a given mechanism with a specific intervention, and the expected effect of such mechanism in the health outcome. This level of potential effectiveness can then be used to sort interventions and prioritize those that deserve more rigorous evaluation (48).

Prototyping can be used to obtain estimates of potential effectiveness of an intervention, that is, of the probability of changing a given mechanism with a specific intervention and of the potential effect of such mechanism in the health outcome. This is one additional reason why it is so important to build and test prototypes early on the design process: it provides experimental data to enrich the evaluation of each potential intervention. Formally, it is known that estimations from observational studies are usually not equivalent to estimations from experimental manipulations (49). Although causal models can help to link estimates from non-experimental data as causal effects, this occurs only when some assumptions are held (50).

An additional benefit of estimating the potential effectiveness of an intervention concept is that it makes the design team aware of their assumptions: Do they really believe that changing the selected causal mechanism will be a necessary and sufficient condition to lead to the desired change in health outcome?

2. Observe: the context, the population, the constraints

The main goal of this process is to further develop the scientific model of the "understand" process into a very specific explanation of the health issue given their context, the population and the healthcare circumstances.

Collect data

The design team collects information to elucidate each element of the canvas: the causal mechanisms underlying the health outcome, the conditions and preferences of the target population and of the healthcare providers, the current dietary practices, and the determinants of those dietary behaviors. Examples of good frameworks for epidemiological analysis include: (10) and for behavioral analysis: (13,51).

During the "observe" process, the target population's needs should be identified (52). This includes defining unmet and latent needs, desires and preferences of the target population. Adopting the user's perspective through *empathy* is one of the most powerful ways to understand people's needs.

Update the scientific model

Because the causal model built in the "understand" process is generalizable and applicable to multiple contexts, it is important to refine it during the "observe" process so that it captures the target population and specific context. This implies updating the relationships between variables. It also includes an update on their relevance, and possibilities of modification. This step is particularly important when using causal reasoning because, as recent advancements in transportability theory suggest, one rarely can transport knowledge obtained under specific circumstances to a different causal context and expect it to be valid. This is especially true when developing new interventions or policies (53). If a structural causal model was created, it will imply an update of the equations and of the non-testable causal assumptions.

Define the problem

Within a causal reasoning, the problem might be defined using the structural causal model: equations, variables, non-testable assumptions, etc. Then, the problem is to identify which change on these causal variables will trigger the desired change in the target outcome. However, within the semantic world of culture and behavior, the problem definition implies a conceptual formulation—not so precise. The DIC can be used as a framework to populate the collected data and progressively define the problem. Figure #3 shows how it looks an analysis of the medical nutrition therapy for diabetes within the Mexican healthcare in 2016.

3. Ideate: generating, nurturing and vetting ideas

In this process, the design team focuses on generating, nurturing and vetting ideas. From a causal perspective, an intervention idea is the replacement of a causal pathway in the

structural causal model with a predetermined value. The implicit statement is that, holding constant all other factors, this change in the causal web will generate the desired outcome (54). The goal is to have a set of high quality, vetted intervention ideas about how to activate the target causal mechanism (given the target context and population) leading to the desired dietary/health goal. The quality of the ideation process should be kept high by using relevant scientific disciplines. The total number and the average quality of ideation seems to be exponentially associated with overall success of the final prototypes (55).

Generating ideas.

The goal in this process is to generate many novel ideas at the outset. Sources of inspiration for brainstorming sessions or other divergent thinking techniques are users' insights, designers' personal experiences, and knowledge from many scientific disciplines. To ideate and build prototypes, the design team can develop a matrix of theoretically based approaches. For example, in behavioral sciences, there are taxonomies of behavior change techniques (56,57) that could be used to generate prototype intervention concepts. A set of behavior change strategies for dietary behaviors is offered in table #2.

Nurturing ideas.

Incubating, deconstructing, mixing and discussing ideas is an important step to help refine initial ideas into more well-defined solution concepts (58). It is critical to allow new, unheard or "unfocused" ideas to be carefully considered, rather than to criticize and reject them too early. This process helps germinate fledgling ideas that may seem highly unusual at first, but could prove to be eventual breakthroughs. This process is highlighted in contrast to traditional processes in which experts tend to gravitate to ideas that promptly seem grounded in available knowledge, discouraging the unfamiliar.

Vetting ideas or solution concepts.

After a set of ideas is obtained and nurtured, they can then be "vetted" or assessed relative to selected intervention criteria such as: likelihood of impact, cost, feasibility, and potential user satisfaction. Scoring and selection can done using conceptual ordinal scales (best, good, fair and poor, or 1-4); or continuous numerical scales (59,60). Once ideas have been nurtured and vetted, a subset of the most promising ideas is carried forward to the build process.

4. Build: transform ideas into prototypes

The build process transforms the set of vetted ideas into prototypes. A prototype can be based on one or multiple ideas. In turn, ideas tend to evolve sequentially through a set of successive prototypes (design branches). The end product of this process is a set of prototypes that are the best available expression of an idea of solution. The quality of the *build* process relies on the team´s skills to build such prototypes, the available technologies and the understanding of the user's needs (25).

Types of prototypes

Dietary intervention prototypes can include healthcare consultations, nutritional supplements, remote support components, cooking tools, etc. There are many ways to "build" such prototypes; they do not need to be necessarily physical prototypes. A mathematical model used for running simulations can be considered as an abstract, analytical prototype (59). Drawings, either of low or high fidelity, can be used to describe the new "dietary service". An imaginary script can be used to walk the participants into a health service that has not been built. Functional prototypes can be made of available objects and with already built premises for healthcare services.

For example, low-fidelity prototypes of smartphones were made with simple drawings; with paper and clips. Functional prototypes were made with big computers connected through wires to heavy touch-sensitive surfaces and then to large screens; together, they provided the function that smartphone eventually would offer. A high-fidelity prototype can be made of expensive materials, closer to the final look and physical properties of the final component, such as 3-D printed models.

Prototypes are also used within other design processes. For example, a prototype can be used to elicit user's feedback during the observation or ideation process, and prototypes are eventually evaluated in the *test* process. In addition, the creative act of building a prototype triggers reflections in the design team, which can lead to deeper insights that generate new ideas, and help vet initial ideas.

Build intervention components

A requirement to build intervention components is to have defined the core level of the canvas and the value proposition. An intervention component prototype can be built for each vetted idea and for each module of the eating stages.

Typically it is better to build rough, inexpensive prototypes early on rather than late on the design process. For example, a vetted idea could be tested with a simple paper prototype. This helps to get feedback from stakeholders, designers and potential users (61). Then, a more sophisticated prototype (computer application or 3-D model, etc.) could be built that incorporates feedback from the initial simple prototype. In this way, progressively more detailed prototypes can be built and iteratively tested at low cost.

Within the DIC, the goal of the build phase is to create a "minimal viable intervention" or MVI. An MVI is a minimal set of intervention components able to trigger the causal mechanism and offer value to the target population. The MVI is analogous to the concept of minimal viable product, which is widely utilized in software and product development (59). Figure #3 helps to review how the proposed MVI supports the target population to achieve the MNT specifications.

It might be very important to emphasize that an MVI built with the DIC is not an object. Rather, designing a dietary intervention should be seen as an experience or a service (62). Old style dietary interventions were based on providing vouchers or a pill with vitamins—an object. Novel interventions that focus on the holistic experience of the end user are likely to

have greater effectiveness. What is intended to be built is a modified dietary practice and supporting it through the intervention.

5. Test: evaluate prototypes and assumptions

The goal of the testing process is to identify the most promising prototypes that also satisfy the minimum viable intervention criteria. There are multiple methods and strategies for such testing related to health interventions. Three types of testing are particularly important during the development of intervention components. The first is analytical testing. A prototype can be tested with regards to their expected effect on the causal mechanism, rates of adoption, costs, etc. In alpha testing, the design team tests the prototypes by themselves. It can be done under experimental settings or by going to live under the circumstances of the target population. Alpha testing can accelerate the identification and iteration process at a fraction of the time and cost of other methods. Then, beta-testing the prototypes with a subset of the target population can be used to further refine prototypes of intervention components.

The design team can also test design assumptions or hypotheses. For example, testing can improve our understanding of the target population's dietary behaviors, or our understanding of MNT specifications. Testing is a critical way to get detailed feedback from user experience about a prototype's functionality, aesthetics, components, usability and changes to improve it. Lastly, the design team can independently test intervention components that, when bundled, represent a minimal viable intervention.

6. Iterate: refine prototypes progressively and systematically

As shown in Figure #1, iteration underscores a foundational concept in design sciences. Problem identification and solution development are mutually reinforcing processes that constantly evolve over time. The iteration process should first focus on improving user/patient satisfaction. Then, the design team can focus on tweaking intervention prototypes and components to achieve the desired physiological or cost levels. This sequence of improvement criteria often leads to less complex design challenges (63). To do so, it is helpful for the design team to identify and use key performance indicators in this process.

Finally, parallel prototyping and iteration under time constraints might increase iteration performance. Both are useful techniques that seem to make the design processes more efficient (64,65). As it is often said, "designers love constraints."

The final product of the design process is not one, but several vetted prototypes for each intervention component. Together these prototypes are intended to comprise the components of a minimally viable intervention. The design team then can develop controlled trials to test the prototypes, such as randomized-controlled trials or fractional factorial trials (66,67).

Discussion

Changing dietary behaviors is notoriously difficult, and dietary interventions—such as those for weight control—often show disappointing results. The Dietary Intervention Canvas (DIC) aims to maximize the likelihood of success when developing such interventions. The DIC adopts an interdisciplinary view of dietary interventions intended to improve the specific translation of novel physiological and nutritional findings into dietary behaviors and then into intervention components. By offering a comprehensive view of all major dietary behaviors (obtaining, processing, ingesting, and preserving food, and fasting), it can help health intervention designers identify better intervention concepts.

Breaking down the causal mechanisms from the MNT specifications and from the specific dietary behaviors to achieve that goal enables the design team to have more latitude to ideate, build and prototype solutions. In contrast, traditional methods to design interventions underestimate the importance of these analytical views. For example, when the goal of the intervention is already defined in concrete dietary behaviors such as "reducing caloric intake through caloric counting" little room for innovative solutions is left, compromising the overall impact of the intervention. The modular canvas of the DIC helps to guide the design team towards a more holistic, more creative approach.

By promoting the use of early, lean and iterative testing, the DIC promotes the design of more effective, feasible dietary interventions. Prior research and empirical reports suggest that, holding constant the skills and resources of the design team, the sooner the prototyping, testing and iteration start, the higher the probability of achieving satisfactory prototypes that meet key performance metrics (64,65). For example, data from industrial design suggest that a minimal increase in the quality of idea generation –achievable with an iterative process- causes a far greater gain in profits (55). By analogy, a small increase in the quality of intervention concepts might lead to large gains in population health. In sum, the use of key design processes might improve the practice of public health, as it has for other disciplines, such as business and computer sciences.

To improve the impact of dietary interventions, the DIC posits the idea that the efficacy, efficiency and adoption of an intervention are inextricably linked and should be considered from the beginning of the design process. The common development methods of pharmacological and behavioral interventions tend to focus first on physiological causality; build initial prototypes under controlled conditions; and consume a large part of the research and development budget on efficacy testing. This traditional approach wrongly assumes that an intervention showing efficacy under controlled conditions will also be successful in real world implementation and adoption—a major reason why health interventions often fail. When that happens, rather than blaming the "operators" of the program, one should blame the "designers" of the intervention.

The DIC is meant to develop supportive interventions, that is, for users who already have the intention and motivation to solve their health issue. If the target users are in a state of psychological inertia and do not have motivation to act, there are a number of theoretical

models that could assist the design team to bring their target users to that psychological status of readiness to change, such as the Transtheoretical Model of Change (68).

The DIC answers the institutional calls for innovation in lifestyle and obesity programs (7,69,70) with a very specific way to use design sciences principles. It embodies the approach of breaking down complex problems into modular, functional and minimalistic units. This approach takes away part of the inherent complexity we face when trying to improve population's lifestyles. It was inspired by similar processes from other fields, such as: an approach to build operative systems (28), a method to develop business models (71), a method to develop social programs using principles of behavioral economics (72), and models and processes ideated to design behaviors for digital services (73).

The more precise and user-centered processes incorporated into the DIC are intended to produce more cost-effective interventions. However, this approach also requires more up-front resources for design and constant evaluation. This is in contrast to traditional planning that overly relies on investigator-initiated efforts that define the intervention components *before* the start of the project. A common recommendation in health policy and program evaluation is to allocate 5% of the program/intervention budget for evaluation purposes. This raises the question about what proportion of resources should be allocated to a design process? A response is that if failure of a health policy or its eventual modification were expensive, then it would be wise to invest generously in early design/prototype/testing/iteration process. This could lead to dramatic reductions in operational and implementation costs, in addition to better outcomes.

The larger and more expensive the failure of a program, the more important is to invest in early design and prototyping. This is the way that the aerospace industry—an industry with expensive development costs and expensive failures—has been disrupted by startups like Space-X. Such startups reduce the risk of failure by innovating, prototyping and iterating as much as they can. It is literally done even at launch time. Public health practitioners should adopt this approach to address not only the incidence but also the prevalence of multiple chronic diseases modifiable by dietary mechanisms. We cannot afford to learn that public health interventions fail only at the end of large, costly trials – only to re-*launch* another large, costly trial. Rather, we should "fail faster, fail earlier, fail cheaper".

In addition, rather than aiming to replace or compete with existing valuable health planning methods, the DIC was designed to be used in concert with more integrative frameworks. It is particularly useful in situations where it is necessary to innovate upon best practices and programs; for example when the level of effectiveness or cost should be dramatically modified. In this case, health intervention designers could use the DIC to generate solution alternatives and then evaluate the generated interventions through their preferred health planning model, such as the PRECEDE-PROCEED model, the behavior change wheel, intervention mapping, or RE-AIM model (13,51,74).

The DIC can easily be integrated into these methods, contributing to the analysis of dietary practices and development of better intervention alternatives before formal and expensive implementation. It enables health designers to break down such interventions into their "active" components, define how each component fits into a causal model of dietary

behavior changes leading to better health outcomes, and to redesign the intervention components quickly and systematically during prototype testing.

Limitations

Proposing a new approach to develop and test dietary interventions is a challenging endeavor, given the long history of failure of such interventions. This first description of the DIC method should be considered an initial version that should be refined over time. The DIC will need significant testing in real world conditions to assess its value and to refine it to improve the practice of designing dietary interventions. We advise that comparative effectiveness studies—possibly conducted by the same design team—be used to measure feasibility, satisfaction and outcome indicators of the DIC.

Conclusion

The proposed DIC is located within the nascent domain of behavioral design: the combination of design and behavioral sciences with health aims (70). The DIC is intended to advance further development and appropriation of design science methods by health intervention planners. The best scenario for using the DIC is one in which the best available alternatives are not satisfactory or require a profound adaptation to work in the target population settings. In this scenario, an attempt to innovate would be the natural answer. The DIC includes improved processes to help health interventionists in this endeavor. It helps them to more precisely define causal mechanisms, generate novel, practical dietary behavioral changes to activate those mechanisms, and carefully test and refine interventions with target populations before they are formally launched. Further research will reveal the true value of this proposal.

List of figures

Figure #1. The design process.

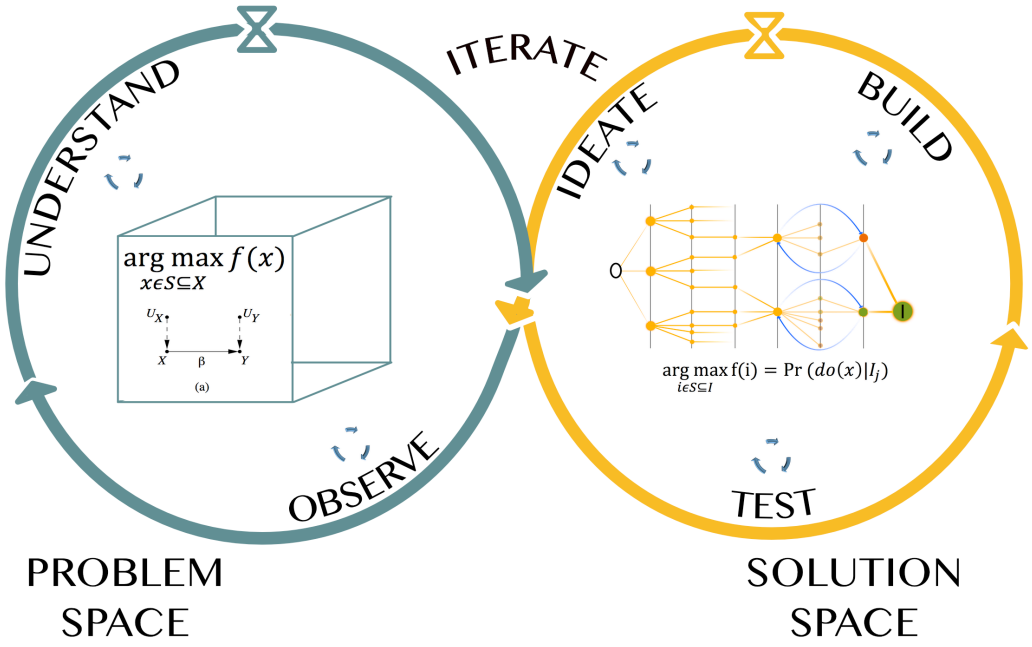


Figure #2. The Dietary Intervention Canvas.

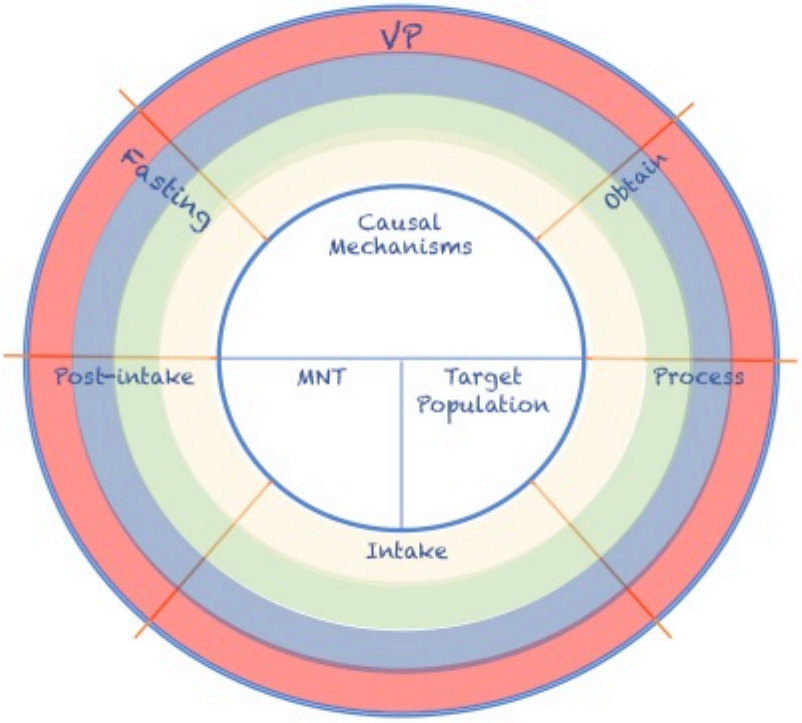
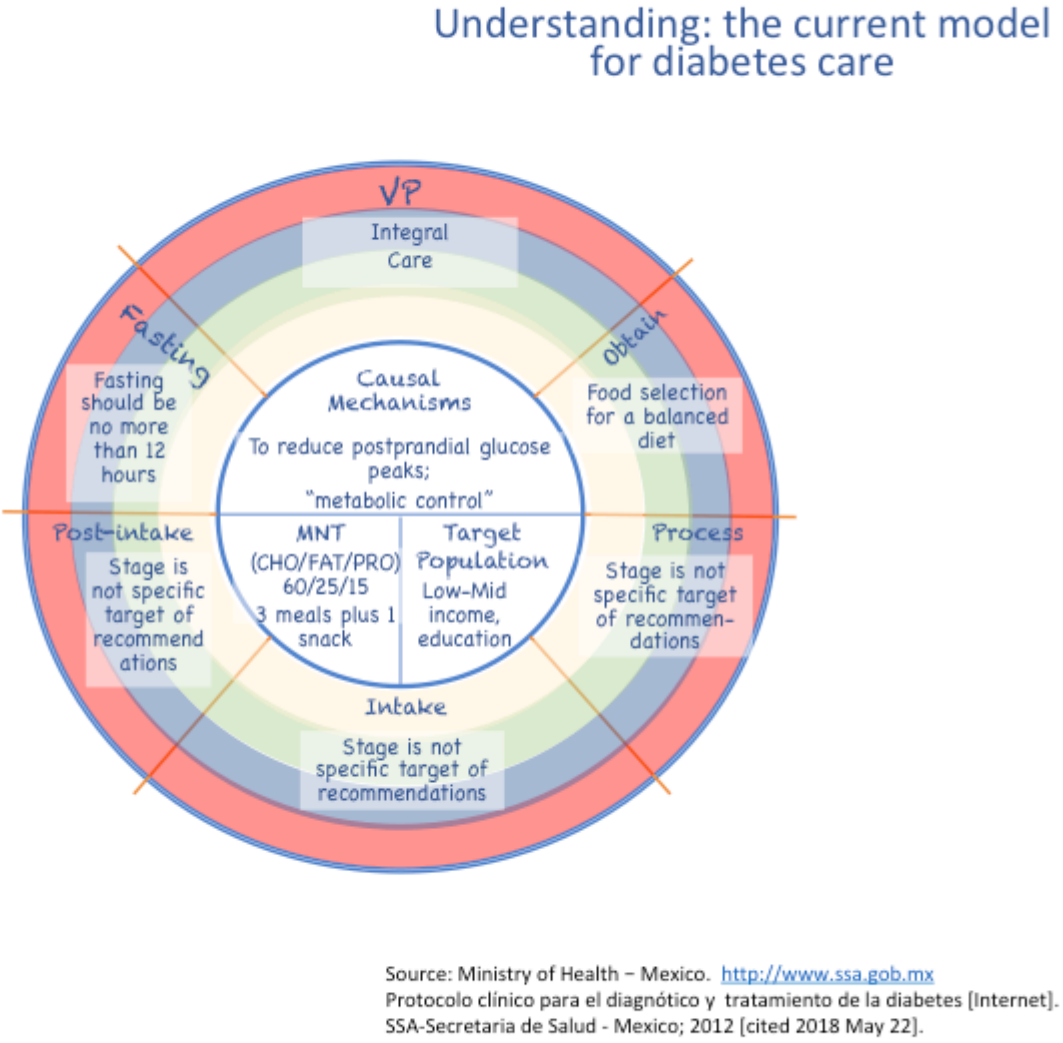


Figure 3. The DIC canvas filled with data about diabetes care in specialized health clinics for metabolic disorders of the Mexican Ministry of Health.



Source: Ministry of Health – Mexico. http://www.ssa.gob.mx
Protocolo clínico para el diagnótico y tratamiento de la diabetes [Internet]. SSA-Secretaria de Salud - Mexico; 2012 [cited 2018 May 22].

List of tables

Table #1. Ideation matrix to construct intervention components, by intervention function

	Strategy	Obtaining	Processing	Ingesting	Post-ingesting	Fasting
1	Feedback					
2	Stimulus control					
3	Contingency management					
4	Transactional cost					
5	Reevaluation of contingencies					
6	Object use					
7	Social support					
8	Leading time					
9	Interpersonal control systems					
10	Counter conditioning					
11	Corrective emotional experiences					
12	Helping relationships					
13	Consciousness raising					
14	Social liberation					
15	Substance use					
16	Bio rhythm synchronization					
17	Body manipulation					
18	Self-liberation					
19	Environmental reevaluation					
20	Dramatic relief					

Source: (75)

Table #2. Set of guiding questions to define the canvas elements

#	Question
1	Causal Mechanism. In physiological terms, what is the target causal mechanism?
2	Target population or customer segment. From all potential beneficiaries/users of the intervention, how do you define your target subset? What are the inclusion and exclusion criteria?
3	Medical Nutrition Therapy specifications. In nutritional terms, what is the overall goal of the intervention?
4	Value proposition. Setting aside the health benefits and from the point of view of the target population, what is the value the intervention is delivering to follow the medical nutrition specifications?
5	Obtaining. In which way is the intervention going to help users perform behaviors related to obtaining food and ingredients?
6	Processing. In which way is the intervention going to help users perform behaviors related to preparing and processing food?
7	Intake. In which way is the intervention going to help users perform behaviors related to serving, measuring and ingesting food?
8	Post-intake. In which way is the intervention going to help users perform behaviors related to food preservation and food waste handle after the ingesting episode?
9	Fasting. In which way is the intervention going to help users to follow proper fasting periods (ultradian/circadian/infradian/periodical)?

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Chapter 4. Remission of type 2 diabetes under economic constraints: results of an iterative design process

Abstract. Novel physiological findings reveal that remission of type 2 diabetes mellitus may be achievable. However, such experimental findings need to be translated into clinically effective interventions. In addition, it is necessary to consider patient characteristics and the cultural milieu of the target population. This paper describes the development of a diabetes remission intervention prototype designed for Mexican patients.

Methods. A new methodological approach, the *Dietary Intervention Canvas*, was utilized to develop the intervention. Six design processes were used to develop prototypes of diabetes remission interventions: observe, understand, ideate, build, test and iterate. The intervention modules specified were: causal mechanisms, target population, value proposition, medical nutrition specifications and dietary practices (structured diet, fasting, obtaining, processing, intake, and post-intake dietary behaviors).

Results. The target host healthcare system was the Mexican Ministry of Health. The design constraints posed by the healthcare system were that the cost per person treated should be less than $2000 USD with a probability of success of at least 20% and compatible with dietary traditions in Mexico. The design process required multiple iterations through physiological, nutritional and behavioral intervention layers. A resulting set of diabetes remission mechanisms was identified, converted into a medical nutrition therapy and then translated into a dietary and fasting regimen with cultural acceptability. The selected physiological mechanisms target the reversal of hepatic insulin resistance, beta-cell function failure, increased autophagy and potentially, beta-cell replication.

Conclusion. The use of design science principles enabled the progressive translation of novel physiological findings into nutritional, dietary and behavioral blueprints for a diabetes remission intervention, helping to identify and address serious barriers that could have compromised the adoption and effectiveness of the intervention.

Introduction

The widespread presence of type 2 diabetes mellitus (t2dm) has become a healthcare crisis worldwide. Its incidence has dramatically increased despite large expenditures in diabetes and obesity prevention. In 1995 it was estimated that the worldwide incidence of t2dm was going to increase by an average of five million per year, reaching 300 million by 2025. However, increased incidence outpaced even that pessimistic projection because by 2015 there were more than 415 million with the disease (1,2). The incidence of diabetes is also increasing among age groups who used to be largely free from t2dm, such as children and adolescents (3). Each case of diabetes generates not only a health impact but also a financial, social and emotional burden (2). Because there has been no known cure, the standards of diabetes care have focused on "managing" the disease; relieving the symptoms and preventing secondary complications without addressing the underlying pathophysiology. This situation is unsatisfactory both for the healthcare sector and patients because chronic "management" of the disease is both more expensive and less effective than curing or suppressing the underlying metabolic deficiencies.

To accelerate research towards a cure, in 2009 a scientific panel convened by the American Diabetes Association formulated an operational definition of cure and remission of t2dm (**rt2dm**) (4). This definition utilizes widely available circulatory biomarkers of glucose homeostasis, facilitating both retrospective and prospective analyses. Very soon it was confirmed that bariatric surgery achieves rates of remission between 30 and 80% during the first year (5). Consolidating multiple lines of research, three major explanatory hypotheses are proposed: caloric restriction, foregut and hindgut hypotheses. The caloric restriction hypothesis states that a major decrease in caloric intake and its associated weight loss promotes rt2dm. The foregut hypothesis states that the changes in the first portion of the duodenum (duodenal exclusion) promote rt2dm. The hindgut hypothesis states that an increased and faster exposure of the distal part of the jejunum and ileum to nutrients increases the secretion of incretins, promoting increased insulin secretion and overall glucose homeostasis. Experiments on the caloric restriction hypothesis have yielded promising results (6–8). The rates of remission obtained in a pilot clinical trial were several orders of magnitude greater than those typically observed in clinical settings (9,10). All together, these findings hold the promise of changing the standards of diabetes care worldwide.

Unfortunately, the history of translating novel and important physiological findings into public health interventions is disappointing. Health innovation has been dominated by pharmacological methods, where a novel treatment agent is tested under controlled conditions, maximizing the ability to measure efficacy (as opposed to effectiveness). Then, the novel treatment agent is released for its dissemination and adoption. *These traditional practices are ill suited for the behavioral, social, and operational nature of multifactorial public health problems* (11,12), hindering the maximum effectiveness achievable in public health interventions.

To improve the translation of novel physiological findings into acceptable interventions for both clinicians and patients, a new design method, the Dietary Intervention Canvas, was utilized (13). To design effective rt2dm interventions, the method has three foci: physiological mechanisms, characteristics of the population and context, and a value proposition. Together, they propose that an intervention not only must have physiological foundations, but also be sensitive to the context and population. Furthermore, the intervention should be appreciated by the target users; otherwise, it risks not having a satisfactory level of effectiveness.

This paper presents the results of using such method to develop a diabetes remission intervention tailored to the Mexican context. The design considered the physiological mechanisms of remission, the social and behavioral characteristics of the target population and the operational settings of the healthcare system.

Methods

The development of the diabetes remission intervention was done using a new methodological approach, the Dietary Intervention Canvas (**DIC**) (13). The DIC empowers health and social sciences scientists with good practices from design sciences such as an iterative, lean and fast approach to build prototypes, in addition to a human-centered design (14–18). From the point of view of implementation science, the DIC facilitates the translation of novel physiological findings into medical nutrition therapies and then into behavioral and operational components.

The DIC consists of a blueprint and a set of specific design processes. The blueprint helps the design team to break down complex dietary interventions into simpler, functional elements (see figure #1). The blueprint contains an internal and an external level. The internal level is intended to assure a minimal efficacy, implementability and adoption of the future intervention. To improve potential effectiveness a three-way focus is proposed: the physiological causal mechanism, the target population and context, and the value proposition of the intervention. These three factors are mutually interdependent: the best definition of one depends on the definitions given to the others. The specifications formulated in this process in turn guide the external level specifications—the dietary behaviors level. Given the medical nutrition therapy specifications, multiple dietary practices could be formulated. However, each dietary practice can be analyzed into five major eating stages: obtaining, processing, intake, post-intake and fasting (19). The intervention design process iteratively considers these stages to find the best set of dietary behaviors given the food environment, the population characteristics and constraints.

To work through the Canvas, the design team uses six different cognitive processes. Each process refers to a different mindset and skillset. These processes can also be referred to as "stages": *understand* the causal mechanisms, *observe* the context and target population, *ideate* novel ideas of solution, *build* prototypes, *test* those prototypes and minimum viable interventions, and *iterate* (13). For each process, a number of research techniques and tools are available (20). Table #1 presents those utilized in this project. Approval for this research

was obtained from the institutional committee for the protection of human subjects, University of California, Berkeley.

Results

The Target healthcare system was the Mexican Ministry of Health. The intervention was designed to be implemented through the UNEMES-EC, a multidisciplinary diabetes care service considered the gold standard within the Ministry of Health. The expectation of the Ministry of Health directors is that the intervention goes beyond metabolic control and achieves the maximum reduction in risk of complications from diabetes, measured with HbA1c levels.

Definition of the design challenge. The goal is remission of type 2 diabetes mellitus, operationally defined as achieving normal levels of HbA1c and fasting serum glucose (FSG < 100 mg/ml [<5.6 mmol/mol] in the absence of ongoing hypoglycemic pharmacological or surgical procedures for at least one year (4).

The design challenge was to design an intervention that could achieve such goal while also satisfying certain financial and operational constraints. Two constraints were defined through interviews with key stakeholders such as healthcare directors, operators and patients. An operational constraint is that the maximum duration of the intervention should be 12 months. A financial constraint is that the cost per person treated should be kept below USD $2000 for the first year and below USD $1,000 a year afterwards. They also suggested that, in order to justify future budget allocations within the healthcare system, any solution should have at least a 20% probability of achieving rt2dm and that unsuccessful cases should also achieve remission levels of HbA1c with the help of a low cost pharmacological treatment.

Design iteration requires guidance through optimization criteria. Based on best practices of user-centered design, we decided to focus first on optimizing patient satisfaction, and then on clinical and financial performance. The rationale to focus first on "customer satisfaction" rather than clinical or operational performance, is that it appears to reduce the complexity of design challenges in future iterations (14,18). This might be due to the finding that subjective metrics -user's satisfaction- are more difficult to measure than objective ones such as financial costs or clinical impact. The design question was formulated as "How can we support people with diabetes to start their path towards remission of the disease through non-pharmacological means?"

Below, we offer a summary of each design process. While it is presented sequentially, in reality the whole process was an iterative one, mutually reinforcing and modifying the other processes after each iteration cycle. Figures 1-5 offer some snapshots of this iterative process.

Understand. In design sciences, the problem space is not equivalent to the solution space. We aimed to understand the causality behind remission of diabetes not the causes of

diabetes. Despite the existence of other alternatives, such as early insulin therapy, a review of scientific literature and consultations with experts concluded that bariatric surgery is the treatment most clearly associated with rt2dm. As a comparison, bariatric surgery outperforms at least 100 fold the incidence of rt2dm obtained in some clinical settings (78.1% vs 0.147%) (5,10). Table #2 provides a summary of the potential physiological mechanisms that could lead to diabetes remission. Of them, the recovery of beta-cell function through a 2-month very low calorie diet is one of the most important ones (21). We cross-referenced the physiological importance of each cause with epidemiological data from the target population. The high prevalence of central adiposity in Mexican populations and the incidence of t2dm with a relatively lower BMI suggest an important role of hepatic fat content and hepatic insulin resistance. Fortunately, the feasibility of reversing this pathology is high. In the liver, a more brief period of caloric restriction could trigger a substantial reduction of ectopic fat and intracellular concentrations of acetyl-CoA; an increase in glycogenolysis and TAG-DAG-PKCe activation. In turn, these effects seem to improve hepatic insulin sensitivity and to reduce abnormal hepatic glucose production (22,23). Since restoring normal liver function appears to be a necessary condition towards remission of type 2 diabetes, we identified this as the target causal mechanism of the intervention (see Appendix A for a description of the component).

Observe. An analysis of the current *status quo* of diabetes care in Mexico was conducted through review of published reports and interviews with key stakeholders. Compared to USA and Europe, the Mexican standards of diabetes care were outdated in the area of medical nutrition therapy. The focus was then narrowed to the specialized medical units on metabolic disorders, or UNEMES (24,25). The operational model of these clinics is a modification of some of the best practices in diabetes care, providing integral care through a team consisting of a physician, a psychologist, a nurse and a nutritionist. However, an analysis of the operational guidelines and of the available usage statistics showed that this approach might not be scalable at the level and cost requested by the stakeholders. Furthermore, although it is not possible to estimate the incidence of rt2dm from available statistics, key stakeholders reported that incidence is likely to be near 1%. After performing interviews with members of the healthcare team, it appears that important points to improve effectiveness of UNEMEs are training of new staff and improvement of the treatment algorithm.

The goal of observing the target population was to understand *what does it take to achieve remission of diabetes given the socioeconomic, cultural and personal context of the target population?* We searched for positive deviants (26)— people with diabetes who had achieved outstanding management and asked ourselves, what factors mediate either success or failure to control the disease? A psychological analysis yielded the hypothesis that continuous social support in the form of cognitive, motivational and instrumental support was necessary (27), since it was reported by most of the POs interviewed in the target population. Social support has been linked to successful weight loss for long time (28), and it seems to be particularly important for Latino populations (29).

To refine these observations, we used a technique we called “alpha-experiencing,” It consists of sending members of the design team to live in the context, under the constraints and daily experience of the target population. The goal is to test the design team’s understanding and mental models (prior assumptions) of the problem (30). This produced

several key insights. Scarce availability of food sources for some key nutrients and lack of body and food scales suggested the need to create an intervention component to deal with these issues. Furthermore, our mental models regarding target population crumbled upon experiencing the constraints of living with less than $2 USD/day. For example, it became evident that giving up on little indulgences, such drinking a soda at the end of the day, was asking too much, given that was the only pleasure that some participants could afford.

Ideate. The ideation process spanned topics including physiology, patient's adherence and healthcare settings. For the causal mechanisms in Table #2, we sought to find out which medical nutrition therapy can trigger them? The design team started an ideation process with a free, open brainstorming approach. Then a steep vetting process followed. Each potential idea was assessed for its physiological plausibility, its feasibility given the financial and operational constraints, and for its alignment with the target population characteristics. In similar way, using the different strategies to trigger and sustain dietary change shown in Table #3, we aimed to determine which combination would maximize the odds that a patient will achieve rt2dm?

Build. Development of prototypes started by reverse-engineering two benchmarking diabetes care interventions: the Diabetes Prevention Program and the Look AHEAD Study (31,32). The architecture of such interventions yielded a blueprint for a minimum viable intervention. Such blueprint has a medical, a psychological and a nutritional component. Also, it has a toolbox of activities and material support for cases of lack of compliance to treatment. Based on observations of the target context and population, it will be necessary to create an additional component to overcome the practical issues of having the tools to measure body weight and food portions, and to address the lack of food sources for certain nutrients at an affordable price point.

A blueprint for a minimum viable intervention based on findings from positive deviants was formulated (see appendix for details). The blueprint follows closely the conclusions arrived through the *understand*, *observe and ideate* processes. It defines a medical nutrition therapy to trigger the target causal mechanism and suggests a diet based on some of the most accessible foods in the target population. In addition, it contains specifications about the kind of behavioral support that the target population might need. To exemplify this, Table #3 shows the strategies to promote short and long-term dietary change, by eating stage. For each stage, a specific set of strategies is proposed. For example, to support the ingesting stage it is recommended to use feedback, stimulus control, social support and leading time strategies. For fasting, it is recommended to use feedback, stimulus control, reevaluation of contingencies, interpersonal control systems, counterconditioning and bio rhythm synchronization. These categories of behavior change strategies were obtained from a theoretical analysis of successful cases of long-term weight loss and dietary change (33).

Iteration and prototype concepts. A key feature of the DIC is the proposal that the selection of causal mechanisms, MNT and implementation strategy opens a wide spectrum of possibilities, especially when it is not done sequentially, but cyclically. Table #4 shows different alternatives that were available during the design process. The best alternatives are highlighted in bold. To select a causal mechanism for remission of type 2 diabetes the criteria was that it could be engendered by MNT, evaluated through literature review and interview with scientific experts. To select a medical nutrition therapy alternative the criteria

was that it had better expected adherence, evaluated through interviews with members of the target population (stated intentions of adherence). To select the dietary strategies to implement such MNT the criteria was cost, estimated through recollection of data from providers. To select potential sources of dietary components the criteria was cultural acceptability and cost, evaluated through interviews and field data. The potential combinations between all the columns of Table #4 yield a set of intervention concepts. Those with more clinical relevance were explored through different cycles.

During one cycle, it was explored how to implement the 2 month very low calorie diet. After interviews with members of the target population, it was found that adherence for 2 months required a person with high resources at the personal and the social network level, rarely seen in the target population. Despite proposing different behavioral support strategies to the interviewees, they continued to state that adherence would be low, especially due to the length of the MNT. Therefore other MNT capable of triggering some of the mechanisms of rt2dm were explored. Eventually, it was found a shorter regimen, a fasting mimicking diet (FMD) for around 7 days. This treatment could reverse hepatic insulin resistance, and probably promoting beta-cell proliferation and/or re-differentiation, paving the road to future improvement towards remission (23,34-35).

During another cycle it was explored how to implement the FMD. The medical nutrition therapy specifications of FMD can be satisfied through multiple dietary practices and foods. The last 3 columns on Table #4 show a few alternatives regarding sources of macronutrients, suggesting multiple combinations. In order to guarantee cultural acceptance by the target population, the diet should be based on foods and food practices well known by the target population. Interviews and simulation on the field provided some insights regarding the definition of the diet components. For example, when doing meal simulations with participants, it became clear that corn, the favorite source of carbohydrates for the target population, had also the higher risk of overeating. Therefore, as one participant put it, it might be better just not to eat it for those days.

Regarding dietary practices, interviews with members of the target population yielded the several insights that lead to favor certain intervention concepts. First, the type of dietary regimen can be built with several classic foods and ingredients, such as fresh veggies, soups, broth, seeds, etc. Second, to increase the appealing in the target population, it was necessary to find a catchy concept, ideally based on traditional Mexican foods. Third, despite being discredited by the medical community, some people remember an ancient tradition of fasting when sick. Therefore, it might be culturally feasible to promote fasting as a health recovery strategy in some rural communities.

Prototype concepts. Based on the alternatives highlighted in table #4, multiple prototypes could be built and tested in a randomized experiment. According to the interviews done, one of the most favored dietary concepts involves the use of avocado as main ingredient of the main dish of the day, *the avocado diet*. It consists of a 7-10 days of a fasting mimicking diet, a very low calorie diet regimen where most of the calories come from mono-unsaturated fat found in avocados. A sample of the first day is shown in Table #5, at around 50% of daily caloric requirements. Intense caloric restriction has been shown to reverse abnormal hepatic glucose production and insulin resistance in humans (22). If the caloric restriction and the particular ratio of macronutrients are carefully selected (34), they

could trigger also a genetic program that might lead to beta-cell re-differentiation and/or proliferation (35). To reduce the risk of nutrient deficiencies, it includes a multivitamin supplement. Since remission of t2dm is associated with a loss of more than 10% of body weight within 8-12 weeks (6,9,21), this diet is meant to be used cyclically, with a recovery period, until the desired weight loss and/or clinical improvement is achieved.

After the intense caloric restriction period, it is recommended to follow a daily practice of time-restricted eating. A concept named the *farmer's regimen* could be useful. Time-restricted eating might sustain some benefits of the intense caloric restriction (36,37). Several decades ago, it was typical for Mexican farmers to go out early morning without breakfast and work from 6 to 11 AM, and then have lunch, mainly composed of veggies, pulses, corn tortillas and a small piece of meat. After a break, more work was done, they returned home walking and an early dinner concluded their caloric intake. The result was a time-restricted eating pattern, where food was ingested only in 8-9 hours of the day.

It is important to note that, even if the avocado diet and the farmer's regimen were the only proposed prototypes, a cycle of progressive refinement would be recommended. In this cycle, the elements in the external level of the canvas would be refined as well.

Test. This development process did not include a rigorous testing of the promissory prototypes. However, the final blueprint was refined through a method called "alpha-testing", in which a member of the design team followed the dietary regimen and documented what kind of support might be necessary. To reduce the cost of prototype iteration, this alpha-testing was performed with functional prototypes. These prototypes consisted of cooking tools, nutritional supplements, self-monitoring tools and information materials, most of them a modification of commercially available versions. To improve testing quality, the member of the design team had also t2dm and underwent the same level of intense caloric restriction as suggested by the dietary regimen. The symptoms, concerns and positive aspects reported by this team member were cross-referenced with clinical guidelines for fasting (38), suggesting a set of issues for clinical practice.

The design process ended with a blueprint and initial alpha-testing of the intervention components. Further work will be performed to test it in a clinical trial with production-ready components.

Discussion

Through the use of the Dietary Intervention Canvas, a medical nutrition therapy was defined that could improve liver insulin sensitivity and beta-cell mass and function. It employs intense caloric restriction and careful defined macronutrient composition. Since weight loss through a caloric restriction diet is the first line of treatment for recently diagnosed t2dm, it should be clinically acceptable to the medical community. The development into a structured diet with many common foods, preparations and a culturally meaningful dietary practice—for example, the farmer's regimen—seems to make the proposed intervention culturally acceptable. Compared to other dietary regimens aiming for diabetes remission, the length of the treatment and its cyclical nature makes more likely to achieve patient´s adherence.

There are some factors suggesting that, compared to the initial ideas, the final blueprint for an rt2dm intervention has increased probabilities of being effective in real settings. The selection and development of ideas of solution was guided by the following equation:

$$\text{Arg Max}_{ijk}\, F\,(E\_CM_i\,,\, E\_MNT_j\,,\, A\_MNT_k\,) = \text{Expected\_effectiveness}$$

Where

E_CM = Efficacy of the causal mechanism i to trigger health outcome

E_MNT = Efficacy of the medical nutrition therapy j to trigger the causal mechanism

A_MNT = Adherence to the MNT under intervention k by the target users in the target context

In other words, from the set of alternative causal mechanisms, nutritional specifications and techniques to modify adherence, we sought to find the combination that maximizes their combined product. Because this combination was not selected sequentially, as it is often the case in other methods that proceed in a unidirectional way (39–41), there was more flexibility to ideate and find the arguments that maximize the equation.

The maximum efficacy of the selected target causal mechanism provides an upper bound to the expected effectiveness of any intervention based on that mechanism. However, failure to translate such mechanisms into a practical dietary regimen or optimize a patient's adherence could reduce such expected effectiveness to zero, in the worst-case scenario.

Expected effectiveness can be defined as efficacy conditional on specific characteristics of the target population and the context, i.e. how prevalent is the causal mechanism? What is the interaction with prevalent population traits? How feasible is its implementation in the population given contextual factors? Finally, adoption refers to the degree by which end users or beneficiaries use or "adhere" to the intervention. Through a series of iterations, which started with rough dietary regimens, we arrived to a final set of promissory prototype concepts. A preliminary evaluation of such concepts on its physiological plausibility, on its value proposition to the target population and on its implementation feasibility at large scale was performed by interviewing a small sample of healthcare providers and members of the target population. However, it is recommended that a larger feasibility evaluation be performed; which was not possible in this study given the financial limitations.

How does this prototype concepts compare to interventions proposed by others? We found only one other intervention that aims to trigger rt2dm through dietary means (42). Both interventions target reduction of liver and pancreatic ectopic fat. However, our prototype highlights the importance of the ratio of macronutrients, the maximum caloric consumption and intake of other nutrient factors and phytochemicals. This is based on sound evidence that careful management of such factors might matter to mimic the beneficial effects of fasting, promote autophagy of malfunction cell organelles, improve beta-cell function and other secondary complications of t2dm (35,36,43). Also, the final dietary regimen takes advantage of foods culturally relevant for the target population as much as possible.

The design process to develop the intervention was cyclical and recursive. The DIC provided a matrix to summarize scientific knowledge, understanding of the target population

and brainstorm ideas for solutions and to formulate prototypes. The DIC was refined iteratively as illustrated in six snapshots of the Canvas (Figures 1-5). The design process showed how unrealistic our initial assumptions were. Early in the process we learned that the target population's economic constraints and the healthcare systems financial limitations required specific intervention components. A typical digital health intervention for diabetes care would not be concerned with lack of resources to buy food or a food scale; as experienced by our target population.

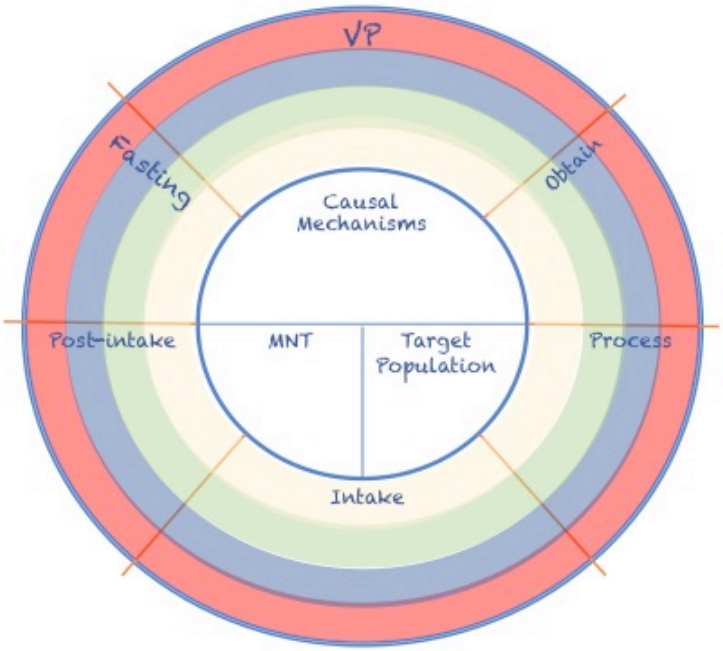
The target physiological mechanisms were modified through the continuous iteration process, eventually leading to methods to reverse fatty liver disease, abnormal hepatic glucose production, hepatic insulin resistance and beta-cell function. Given the challenge of rt2dm, we hypothesize that by adhering to the proposed mechanisms, people with diabetes will be one step closer to achieving that goal. An intervention component to reverse peripheral insulin resistance and perhaps a component of pharmacological support might be necessary to achieve stable rt2dm. Further experimentation is required to evaluate and refine different prototypes based on the blueprint outline in this paper, eventually selecting those with the most expected effectiveness to run a randomized clinical trial.

Conclusions

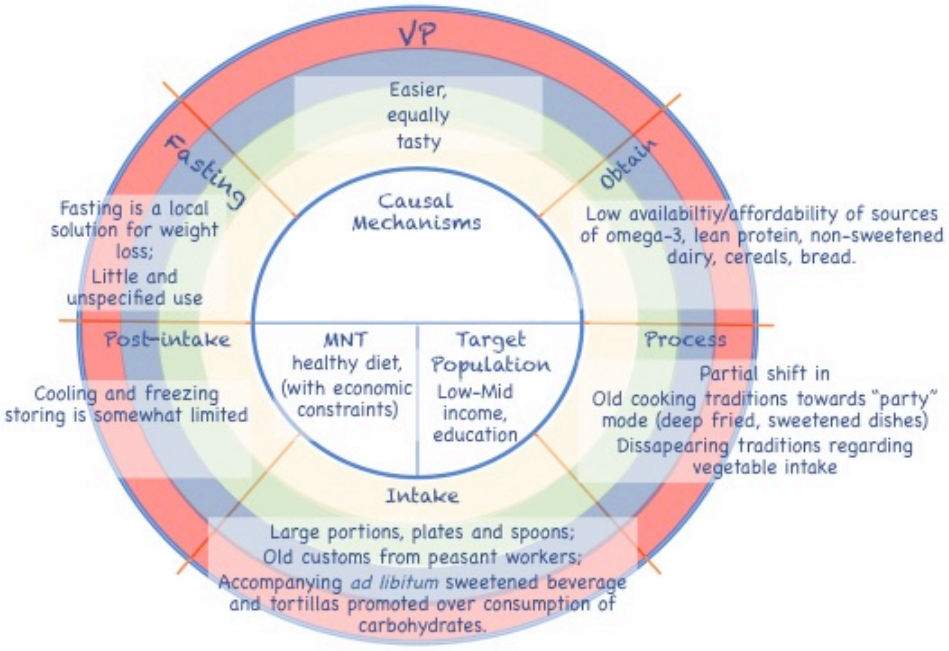
Given the rapid increase of type 2 diabetes globally and its concomitant overwhelming human and financial burdens, it is critical to investigate approaches that can lead to its remission. However, translating important physiological and medical findings into clinical level dietary rt2dm interventions has been difficult. One reason is that developing effective interventions requires addressing multiple complex targets at the same time: physiological effects, nutritional specifications and treatment adherence. This study suggests the value of drawing on design science theory and methods to iteratively develop and test intervention prototypes to manage this complexity. We suggest that the resulting Dietary Intervention Canvas (DIC) is a promising rt2dm approach and merits rigorous clinical testing. We recommend that researchers and practitioners consider not only using the DIC for rt2dm interventions, but also using the overall design process described in this study to address other health and nutrition problems.

Figures and Tables

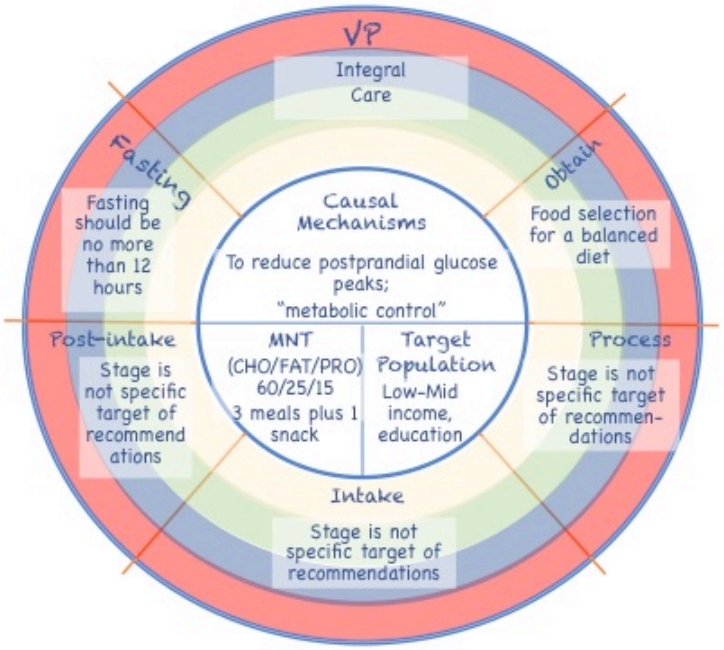
Figure #1 to #5. Dietary Model Canvasses showing the work through the design process



Observing: current dietary practices of the target population

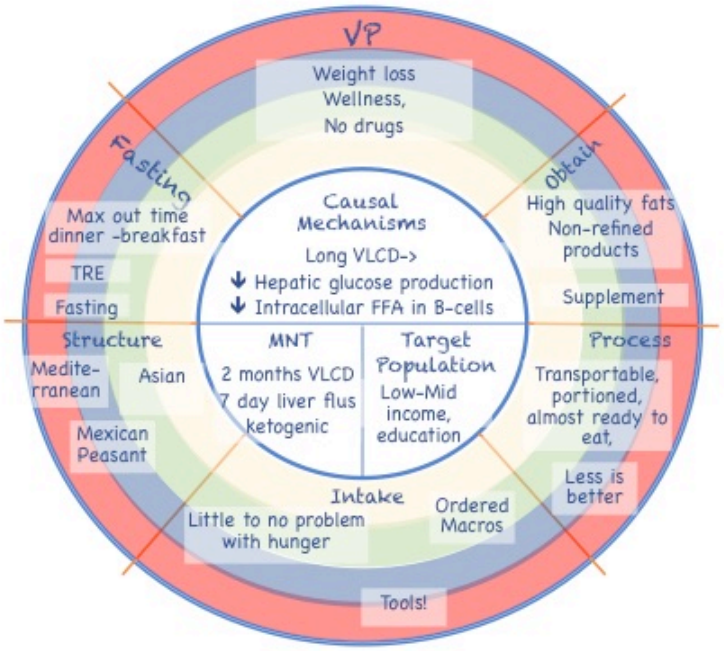


Understanding: the current model for diabetes care



Source: Minister of Health – Mexico. http://www.ssa.gob.mx
Protocolo clínico para el diagnótico y tratamiento de la diabetes [Internet]. SSA-Secretaria de Salud - Mexico; 2012 [cited 2018 May 22].

Ideating: concepts for a diabetes remission intervention



Test: results of alpha-testing prototype for rt2dm

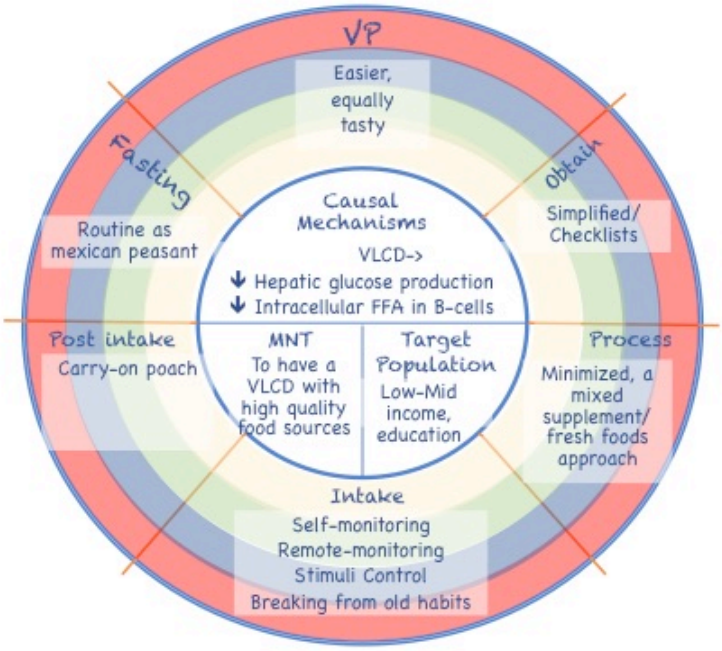


Table #1. Techniques utilized in each design process

Process	Techniques
Understand	Interview with subject experts; review of national norms for diabetes care; review of operations manual of the specialized medical units for the treatment of metabolic diseases; interviews with key stake holders of the healthcare service, with previous implementers of metabolic interventions. Benchmarking current model of diabetes care.
Observe	Non- invasive observation of natural, built and social environment. Qualitative interviews with patients; customer journey through the health service; alpha experiencing a day in the life of the target population. Quantitative surveys to understand physical and dietary activities.
Ideate	Reverse engineering and benchmarking of available experimental interventions to achieve rt2dm or management of the disease. Compilation of local solutions for weight loss. Compilation of evidence-based methods for long-term weight loss. Use of biological inspiration, use of analogies with computational and mathematical problems.
Build	Treatment prototypes; low-fidelity prototypes for self-monitoring of adherence to treatment, low-fidelity prototypes of software-based components. High fidelity prototypes of digital therapeutics components.
Test	Alpha testing of treatment plan; alpha testing of intervention components. User's feedback in low and high fidelity components.
Iterate	First iteration: testing operations and implementation problems. Second iteration: testing patient's issues with compliance and adherence to treatment Third iteration: testing underlying physiological model for diabetes care. Fourth iteration: developing novel interventions targeting remission mechanisms

Table #2. The solution space of type 2 diabetes mellitus. Selected remission mechanisms from bariatric surgery and likelihood of engendering given the design constraints

Category	Timeline	Organs/cells	Effect	Causal factor for rt2dm	cost < $2000 USD	duration < 12 months	Feasibility of engendering mechanism in target population and context
Rerouting ingested food	less than 24 hours	jejunum/L cells	increased and faster exposure to nutrients	+ incretin secretion. I.e. GLP-1 secretion (~20x up to 12months)	0	1	0
	less than 24 hours	jejunum	increased and faster exposure to nutrients	+ afferent signaling to hypothalamus -> + insulin signaling	0	1	0
	less than 24 hours	duodenum	reduced exposure to nutrients	- secretion of glucotropic incretins. I.e. glucagon	0	1	0
Highly reduced caloric intake	weeks prior and after	Liver	reduced hepatic fat	+ hepatic insulin sensitivity	1	1	1
	weeks prior months after	Pancreas/B-cells	reduced pancreatic fat	+ insulin production	1	1	1/2
	during first 12 months	Pancreas/B-cell	increased glucose sensitivity	+timely insulin secretion; afferent signaling to hypothalamus	1	1	1/2
	aprox after three months	overall body mass	reduced fat and body mass	+ peripheral insulin sensitivity	1	1	1/2
rerouting digestive fluids	less than 24 hours	duodenum	decreased exposure to nutrients	- secretion of inhibitors of insulinotrophic incretins	0	1	1
reducing gastric volume	less than 24 hours	stomach	increased satiation; decreased food intake	+ weight management	1/2	1	1

Values 1=most likely, 1/2=somewhat likely, 0=most unlikely

Source: www.diabetesremission.org

Table #3. . Blueprint to construct intervention components, by eating stage

	Strategy	Obtaining	Processing	Ingesting	Post-ingesting	Fasting
1	Feedback			X		
2	Stimulus control	X		X	X	X
3	Contingency management				X	
4	Transactional cost	X	X			
5	Reevaluation of contingencies				X	
6	Object use		X	X		
7	Social support	X	X	X		
8	Leading time		X	X		
9	Interpersonal control systems					X
10	Counter conditioning					
11	Corrective emotional experiences					
12	Helping relationships					
13	Consciousness raising					
14	Social liberation					
15	Substance use			X		X
16	Bio rhythm synchronization					X
17	Body manipulation					
18	Self-liberation					
19	Environmental reevaluation					
20	Dramatic relief					

Reference: (13)

Table #4. Sample list of alternatives to build prototype concepts.

Causal factor for rt2dm	MNT	Dietary strategy	Source of Mono unsaturated fat	Source of carbo-hydrate	Source of protein
+ incretin secretion. I.e. GLP-1 secretion (~20x up to 12months)					
+ incretin secretion. I.e. GLP-1 secretion (~20x up to 12months)		Diet in clinical settings	**Avocado**	**Corn**	**Sardines**
+ afferent signaling to hypothalamus -> + insulin signaling		**Liquid Diet with supplements**	**Olive oil**	**Rice**	Tuna
- secretion of glucotropic incretins.		**Liquid diet,**	Avocado oil	**Beans**	**Protein**
I.e. glucagon		**Home-made**			**supple ment**
+ hepatic insulin sensitivity	**2mVLCD FMD**	**Water Fast**	Macadamia nuts, oil	Wheat	Red meat
+ beta cell FFA concentration reduction	**2mVLCD**	**Structured Diet**			
+ beta cell sensitivity to glucose	**2mVLCD ***				
+ beta cell proliferation	**FMD***				
+ peripheral insulin sensitivity	**FMD**				
- secretion of inhibitors of insulinotrophic incretins					

2mVLCD: 2-month very low calorie diet.
FMD: fasting mimicking diet of between 5-9 days.
*As suggested by data from animal models and cell experiments.

Table #5. Sample of the proposed dietary regimen (Day 2 at 25% of daily caloric requirements)

Time	Food	Grams
	Chia	24
10:00	Protein supplement at 80% (vegan)	8
	Stevia+glucose (1g)	1
	Oats	10
	Hazelnuts	5
	Broccoli	90
	Lettuce / Green leaves (cilantro, parsley)	50
14:00	Avocado	25
	Carrots	50
18:00	Broccoli	90
	Lettuce / Green leaves (cilantro, parsley)	50
	Hazelnut	5
	Olive oil	5
	Carrots	50
	Rice, dry weight	40
	Avocado	30
	Chocolate 70% cacao	10

Appendix A: Final specifications of the dietary model canvas for rt2dm (phase 1)

CORE LEVEL

Causal Mechanism

Intense caloric restriction for 5-9 days generates a:
Reduction of Acetyl CoA
Reduction in TAG, DAG
Reduction in PKCe (protein kinase) activation
Improvement in hepatic insulin sensitivity
Reduction of hepatic gluconeogenesis
Decreased pyruvate carboxylase flux
Reduction of hepatic glycogenolysis

Medical Nutrition Therapy Specifications

Very low caloric regimen that mimics fasting effects
Duration of at least seven days, under stress-free conditions
Caloric intake capped at maximum of 25% of the daily requirements
Maximum calories from protein: 15%
Maximum calories from carbohydrates: 55%
Proper micronutrient intake
Fortified with omega-3 essential fatty acids
Restricted to null intake of: processed carbohydrates, fructose, trans fat, metabolic disruptors;

Target population and customer segment

a. Have a well-defined decision to achieve the goal of the program, i.e. an intention stage to achieve rt2dm;
b. Have perceived self-confidence they could follow a very low calorie diet (VLCD)
c. Are willing to use a commitment device.
d. Have less than 6 years from diagnosis of t2dm;
e. $6.5 < HbA1c < 10\%$;
f. $25 < BMI < 35$;
g. Are non-insulin dependent;
h. Do not have other diagnosis that could hinder compliance or trigger negative treatment side effects: hypothyroidism, chronic renal failure, hypotension, muscular metabolism diseases and a few others.

Value Proposition

For people who aim to achieve remission of diabetes, we offer an intervention that reduces the time, cost and effort of following the appropriate medical nutrition therapy. We offer the cognitive, motivational and instrumental support that is necessary for them to succeed. We also offer a "belonging" social support, the sense of becoming part of a group with similar but larger aims than the personal goal.

EXTERNAL LEVEL

Blueprint to support each eating stage

Stage	**Practical goals**	**Type of intervention support**			
		Instrumental	**Cognitive Support**	**Affective**	**Belonging**
Obtain	Pre-obtained, easy to carry	Provision of key ingredients	Simplified food selection: checklists, structured meals	Peer support	Peer support groups
Process	Transportable, portioned, almost ready to eat	Provision of key cooking and preserving tools	Simplified cooking: mixing, heating and basic fresh foods preparation	Peer support	Peer support groups
Intake	Stimuli Control, context disruption to break with old habits	Provision of key serving tools	Simplified intake: most portions are premeasured. Simplified remote-monitoring: picture based. Simplified temptations control: stimuli and contextual manipulation in advance.	Peer support	Peer support groups
Post-intake	No left-overs, premeasured portions, carry-on foods	Provision of carry-on food containers	Carry-on food to avoid influences of the obesogenic environment	Peer support	
Fasting	Maximize time between dinner and breakfast	Provision of powders for soups and drinks; hunger inhibitors.		Cultural link to the routine of a Mexican farmer from the time of the revolution.	Peer support groups

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Chapter 5. Conclusion and future research

The goal of this dissertation was to develop a method for innovation in the area of dietary interventions in public health. Findings from in-depth interviews of successful cases of dietary change and weight loss suggested relatively novel approaches to promote dietary change, not mentioned by health behavior theories. Using these findings and principles of design sciences, the Dietary Intervention Canvas (DIC) proposes a new approach to study and modify dietary practices. A way to implement the DIC, a prototype of intervention for diabetes remission was developed. The DIC facilitated the navigation through the complex causality behind diabetes and identified a causal mechanism of remission, actionable with medical nutrition therapy. In turn, the DIC facilitated its translation into specific types of dietary behaviors. The prototype fits within the constraints of the Mexican context.

The first paper contributes to filling in the gap regarding what theoretical mechanisms are more appropriate to support dietary behavior change. Positive outliers described a far more varied range of strategies than those considered by the Transtheoretical model of behavior change. The set of categories identified in this paper can fulfill a role as a theoretical matrix to seed the ideation process during the development of novel dietary interventions.

The second paper presented a method that incorporates design sciences principles into public health methods. It addressed the questioning that health sciences experts expressed early on the dissertation work: to consider causal mechanisms with rigor. Finding the right way to convey principles of design and translational sciences into a method for dietary interventions was an iterative, evolutionary process. The canvas provides guidance for the health scientist and it also represents a new way to frame dietary practices.

The application of the DIC in the third paper yielded an intervention prototype for remission of type 2 diabetes. This intervention could be considered innovative, as per the operational definition of innovation utilized in this dissertation. Achieving remission of diabetes would be clinically far better than management of the disease. In addition, the prototype proposes to achieve this with less expensive and less risky procedures than some pharmacological and surgical treatments. Through medical nutrition therapy, it triggers changes in metabolism and genetic expression. As with any innovation, the type 2 diabetes remission intervention will face skepticism from the scientific community. Only formal trials will reduce uncertainty and estimate its real effectiveness.

Future actions and research

This work underlines important implications for future public health practice and research. In practical terms, in order to solve our most urgent health population problems, this dissertation suggests changes in the allocation of resources and funding. The concept of having a problem definition cycle and a solution development cycle is not widespread in public health, especially with stakeholders. Rather than allocating the vast majority of

funding to the problem definition cycle, public health stakeholders should allocate funds to the solution development cycle.

In the area of methods specific to dietary interventions, a new way to define dietary intervention goals was suggested. Defining interventions goals based solely in terms of micro and macronutrients promotes confusion among scientist and open population. We should aim for a definition at a physiological level, along with a medical nutrition therapy specification. In turn, multiple diets might fit these specifications, but it will become clear which diets will not. This might also contribute to increase effectiveness of interventions because it will enable better cultural, economic and operational implementation of such interventions. More research is needed to verify this methodological proposal.

Future theoretical research should explore if the methods proposed in this dissertation yield better results than the current methods to design dietary interventions. In essence, this dissertation´s proposal can be reduced to two main falsifiable assertions:

1. In order to reduce the level of uncertainty when exploring novel mechanisms to solve a health problem, one could focus on those areas within the causal space where a local maxima — or minima — occurs. That is the case of positive outliers of dietary change, weight loss or diabetes remission. They represent data points where the complex causal web yielded the desired value or outcome. By carefully examining such cases, novel hypotheses on how to replicate such outcome can be formulated. This can be done even before the causal pathways are clearly understood. It applies for physiological causality and for behavioral causality.

2. Once novel hypotheses of a solution are identified, an iterative process with early and low cost experimentation yields better results than a more careful process with experimentation only at the end of the process.

The first assertion comes from the study of algorithms for resolution of complex equations through numerical computation rather than formal methods. For some of these equations, no formal solution exists yet. But by applying computational power, a “good enough solution” could be identified. This indeed could describe the panorama when seeking a cure for diabetes: a very complex causal web with no known formal solution.

The second assertion comes from observational and quasi-experimental data from design sciences. Holding constant resources and time, it is more likely that an iterative solving process of multiple cycles of feedback yields a better solution than a more systematic solving process with only one cycle.

A potential way to explore the validity of these assertions would be to design an experiment with teams of health scientists.

Scientists will be randomly allocated to design teams, which will be the unit of experimentation and analysis. The treatment conditions will be the method used to develop dietary interventions: the DIC versus traditional methods of design. The outcome is the quality of the interventions designed by the teams. The controlled conditions will be the resources and time to design each intervention. Two different problems A and B, not related

to each other, will be defined. Fifty percent of the design teams will aim to solve first problem A, with traditional methods and then problem B with the Dietary Intervention Canvas. The other fifty percent of the design teams will aim to solve first problem B with the traditional methods and then problem A with the Canvas. A panel of target users will then judge which solutions the like the most. Assuming the design teams are comparable in skills and knowledge, it will be possible then to assess whether the DIC contributes to generate better results or not.

If these two assertions turn out to be true, the DIC might offer a competitive advantage over other available methods to develop dietary interventions.

Lastly, this dissertation is just but one more attempt to improve health promotion intervention methods. I thank the UC Berkeley campus for enlightening my work. Nothing could be more descriptive of this dissertation than the quote:

"Enlightened trial and error outperforms the planning of the lonely genius" (Peter Skillman).